

Exhibit A

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

KIMBERLY C. CUTONE, and  
ANTHONY CUTONE

Plaintiffs,

v.

ELI LILLY AND COMPANY, *et al.*

Defendants.

CIVIL ACTION No.

**NOTICE OF FILING CERTIFIED COPIES OF STATE COURT PAPERS**

Pursuant to 28 U.S.C. § 1446, defendant Eli Lilly and Company hereby files certified copies of all records and proceedings in the Superior Court action (Superior Court for the District of Columbia Civil Action No. 04-0005308) on file as of the morning of August 9, 2004.

Respectfully submitted,

ELI LILLY AND COMPANY

  
\_\_\_\_\_  
Lawrence H. Martin, D.C. Bar No. 476639  
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Washington, D.C. 20006-1238  
(202) 223-1200

and

James J. Dillon, D.C. Bar No. 485593  
Foley Hoag LLP  
155 Seaport Boulevard  
World Trade Center West  
Boston, MA 02210-2600  
(617) 832-1000

Dated: August 12, 2004

**CERTIFICATE OF SERVICE**

I certify that on August 12, 2004, a true copy of the foregoing Notice of Filing Certified State Court Papers was served by U.S. First Class Mail, postage prepaid, upon:

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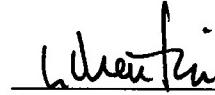
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Washington, DC 20005  
**Attorney Wyeth-Ayerst Laboratories**

  
\_\_\_\_\_  
Lawrence H. Martin

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
Civil Division

KIMBERLY C. CUTONE, and  
ANTHONY CUTONE  
54 Gould Street  
West Roxbury, MA 02132

Plaintiffs

v.

ELI LILLY AND COMPANY  
Lilly Corporate Center  
Indianapolis, IN 46285  
w/s/o NATIONAL REGISTERED AGENTS, INC.  
1090 Vermont Avenue, NW, #910  
Washington, DC 20005

and

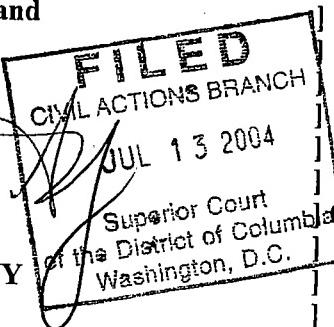
BRISTOL-MYERS SQUIBB COMPANY  
a successor of E.R. SQUIBB & SONS, INC.  
P.O. Box 4500  
Princeton, NJ 08543  
w/s/o CT CORPORATION  
1025 Vermont Avenue, N.W.  
Washington, D.C. 20005

and

PHARMACIA and UPJOHN COMPANY  
(aka THE UPJOHN COMPANY)  
100 Route 206 North  
Peapack, NJ 07977  
w/s/o CT CORPORATION  
1025 Vermont Avenue, N.W.  
Washington, D.C. 20005

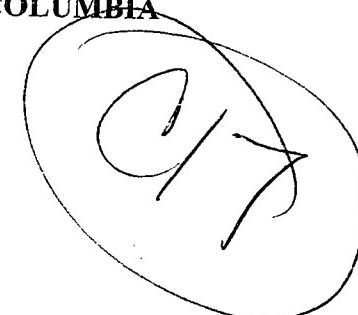
and

DART INDUSTRIES, INC. a successor to  
REXALL DRUG COMPANY, INC.  
14901 South Orange Blossom Trail  
Orlando, FL 32837  
w/s/o Sheila AnnMarie Moeller, Esq.  
Gilbride, Tusa, Last & Spellane, LLC  
31 Brookside Drive  
Greenwich, CT 06836



Civil Action No.

0605307-03



and ]

**PREMO PHARMACEUTICAL  
LABORATORIES, INC.** ]

w/s/o Corporation Trust Co. ]  
820 Bear Tavern Road ]  
West Trenton, NJ 08628 ]

and ]

**WYETH-AYERST LABORATORIES** ]  
**P.O. Box 8299** ]  
**Philadelphia, PA 19101** ]

**COMPLAINT**

**(DES Litigation – Products Liability, Market Share Liability, Punitive Damages)**

1. Jurisdiction is founded upon 11 D.C. Code §921 (1981 ed.)
2. Defendants are engaged, or have been engaged, in the manufacturing, marketing, sale, promotion, and distribution of pharmaceuticals throughout the United States, and are doing business in the District of Columbia, and sought and obtained industry wide and governmental approval for Diethylstilbestrol ("DES") within the District of Columbia.

**COUNT I**  
**(Negligence)**

3. On or about 1969 or 1970, during her pregnancy with Kimberly C. Cutone, the mother of the Plaintiff herein ingested Diethylstilbestrol ("DES") in Massachusetts. Her physician prescribed said drug during the pregnancy. The Defendants, shared the market, manufactured, compounded, packaged, labeled, supplied, sold and advertised DES throughout the United States and the state of Massachusetts. Anthony Cutone is the husband of female Plaintiff, Kimberly Cutone, married in 2001.

4. As a result of Plaintiff's embryonic exposure to DES, she suffered injuries, including, uterine and cervical malformations, infertility, several miscarriages, and incurred medical expenses for care and treatment, and suffered physical and mental pain and suffering.

5. Said injuries were the result of the negligence of Defendants, including, but not limited to, failure to test, failure to warn, over-promotion of DES, and failure to report adverse studies regarding the safety and efficacy of DES.

**COUNT II**  
**(Strict Liability)**

6. All of the allegations contained in Count I are realleged and incorporated herein by reference.

7. DES is, and at all times relevant to this action was, an unreasonably dangerous and defective drug when used by pregnant women for its advertised and intended purpose as a preventative of miscarriage.

8. Defendants are engaged or have been engaged in the business of producing DES, and are, or have been, commercial manufacturers of said drug.

9. Plaintiff's mother purchased and ingested DES during her pregnancy with Plaintiff, and received and ingested DES in the same form and condition as when it left Defendants' possession.

10. Said product was defective when placed on the market by Defendants. DES was sold by Defendants without sufficient warning or instructions. A reasonable seller would not have sold the product had he/she known of the risks involved. The risks were greater than a reasonable buyer would expect.

11. Defendants knew, or should have known, that pregnant women and their attending physicians could not realize and could not detect the dangerous and harmful nature of

DES. Clear warnings as to the doubtful efficacy of DES and dangers to unborn children should have been disseminated to overcome Defendants' extensive advertising campaigns proclaiming the safety and efficacy of DES.

12. As a result of Defendants' marketing and promotion of said defective and unreasonably dangerous drug, Plaintiff was unreasonably exposed to DES as an unborn child and suffered injury, loss, and damages as aforesaid.

13. By reason of having marketed and promoted DES in its defective and unreasonably dangerous condition, Defendants are strictly liable to Plaintiff for her DES-related injuries, losses, and damages.

**COUNT III**  
**(Breach of Warranty)**

14. All of the allegations contained in Counts I and II are realleged and incorporated herein by reference.

15. At all times relevant to this action, Defendants marketed and promoted DES accompanied by implied and express warranties and representations to physicians and their patients that the drug was efficacious as a miscarriage preventative, and was safe for pregnant women and their unborn children if used as directed for such purposes.

16. Defendants knew, or should have known, that pregnant women, including the mother of Plaintiff and her attending physicians, were relying on Defendants' skills and judgments, and the implied and express warranties and representations.

17. At all times relevant to this action, these implied and express warranties and representations were false, misleading, and unfounded. In fact, DES was a misbranded drug in violation of federal law, and was neither safe nor efficacious as a miscarriage preventative.

18. As a direct result of the breach of warranties by the Defendants, Plaintiff has been injured as aforesaid.

**COUNT IV**  
**(Misrepresentation)**

19. All of the allegations contained in Counts I, II, and III are realleged and incorporated herein by reference.

20. Defendants represented to pregnant women, including the mother of Plaintiff and her attending physicians, in promotion campaigns, advertisements, labeling, and literature that DES was safe, effective, and adequately tested, which representations were made and publicized with the purpose and intent of having physicians and their patients rely on them.

21. The mother of the Plaintiff and her attending physicians, did, in fact, rely on Defendants' representations in his advice about purchase, use, and consumption of DES.

22. At all times relevant to this action, these representations were known to Defendants to be false or they were made by Defendants in conscious, reckless and/or unreasonable disregard of facts available to Defendants, indicating a lack of efficacy and a danger to pregnant women and their unborn children.

23. As a direct result of said false representations by Defendants, Plaintiff was injured as aforesaid.

**COUNT V**  
**(Punitive Damages)**

25. The acts of Defendant were gross, wanton and intention in that Defendant, at the time of Plaintiff's exposure, had actual and constructive notice that DES crossed the placental barrier and adversely affected and stunted the morphology and embryologic development of the exposed female fetus. Additionally, the Defendant knew or should have known that DES was

ineffective, of no use and provided no benefit to the pregnant mother. Nonetheless, the Defendant knowingly and intentionally promoted DES for use in pregnancy as safe and effective to prevent the threat of miscarriage disregarding the published literature that warned of the risks and criticized its efficacy. The Defendant intentionally, maliciously and wantonly promoted DES for use in maintaining pregnancy as the most "effective" therapy to prevent miscarriage and even recommended its use prophylactically even where no symptoms or signs of a threatened miscarriage appeared. Additionally, the Defendant fraudulently deceived the Food and Drug Administration and the obstetrical profession and Plaintiff by knowingly and intentionally withholding adverse literature and studies and submitting only favorable reports, which it knew originated in erroneous studies with incompetent investigators using poorly designed test methods.

**COUNT VI**  
**(Loss of Consortium – Anthony Cutone)**

26. All of the allegations contained in Counts I, II, III, IV and V are realleged and incorporated herein by reference.

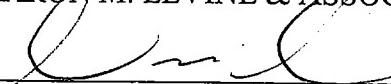
27. Plaintiff Anthony Cutone is the husband of Kimberly Cutone. As a result of the negligence, strict liability, breach of warranty and misrepresentation of the defendant as aforesaid, Plaintiff Anthony Cutone has been deprived of the love, services and affection of his wife, Kimberly Cutone.

WHEREFORE, Plaintiff Kimberly Cutone, individually, demands judgment against Defendant in the sum of Two Million Dollars (\$2,000,000.00) in compensatory damages, Two Million Dollars (\$2,000,000.00) in punitive damages, jointly and severally, plus costs, and

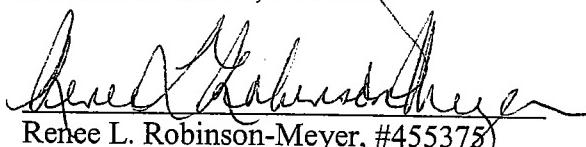
WHEREFORE, Plaintiff Anthony Cutone, demands judgment against Defendants in the sum of One Million Dollars (\$1,000,000.00) in compensatory damages, jointly and severally, plus costs.

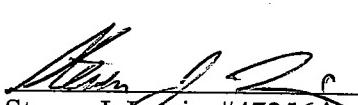
Respectfully submitted,

AARON M. LEVINE & ASSOCIATES

  
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Washington, D.C. 20036  
(202) 833-8040

  
Brandon J. Levine, #412130

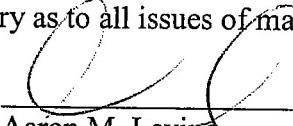
  
Renee L. Robinson-Meyer, #455375

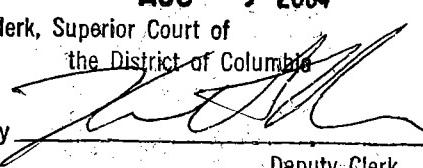
  
Steven J. Lewis, #472564

Counsel for Plaintiff

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a trial by jury as to all issues of material facts.

  
Aaron M. Levine

A TRUE COPY
TEST:
AUG 9 2004
Clerk, Superior Court of
the District of Columbia
By 
Deputy Clerk

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA

KIMBERLY C. CUTONE, et al.,

Plaintiffs,

v.

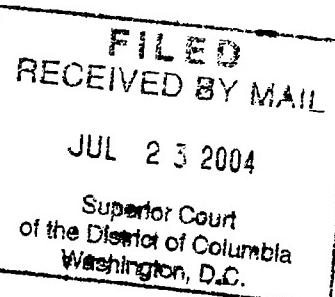
ELI LILLY AND COMPANY, et al.,

Defendants.

Civil Action No. 04ca05307

Calendar # 2

Judge Michael L. Rankin



**ANSWER OF DEFENDANT DART INDUSTRIES, INC.**

Defendant Dart Industries, Inc., (formerly known as Rexall Drug Company, hereinafter referred to as "Dart"), by counsel, for itself alone and denying knowledge or information sufficient to form a belief with respect to allegations concerning any other defendant in this action, answers the Complaint herein as follows.

1. Dart is without knowledge or information sufficient to form a belief as to the truth of the averments contained in paragraph 1 of the Complaint and therefore Dart denies those averments.

2. In response to the averments contained in paragraph 2 of the Complaint, Dart admits that Rexall Drug Company sold and distributed the pharmaceutical product DES between 1949 and 1969, and manufactured DES between 1949 and 1967, if the term "manufacture" is defined to include the process of adding inert ingredients to the bulk active chemical produced by and purchased from others and that in the past Dart has done business in the District of Columbia. Except as specifically admitted, Dart denies the allegations contained in paragraph 2 of the Complaint.

3. In response to the averments contained in paragraph 3 of the Complaint, Dart admits that Rexall Drug Company sold and distributed the pharmaceutical product DES between 1949 and 1969, and manufactured DES between 1949 and 1967, if the term "manufacture" is defined to include the process of adding inert ingredients to the bulk active chemical produced by and purchased from others. Dart denies that it acted in concert with the other defendants or that it advertised DES. Dart is without knowledge or information sufficient to form a belief as to the truth of the remaining averments contained in paragraph 3 of the Complaint and therefore Dart denies those averments.

4. Dart denies the averments contained in paragraphs 4 and 5 of the Complaint.

5. In response to the averments contained in paragraph 6 of the Complaint, Dart hereby incorporates by reference its responses to paragraphs 1 through 5.

6. Dart denies the averments contained in paragraph 7 of the Complaint.

7. In response to the averments contained in paragraph 8 of the Complaint, Dart admits that Rexall Drug Company manufactured and produced DES between 1949 and 1967, if the terms "manufacture" and "produce" are defined to include the process of adding inert ingredients to the bulk active chemical produced by and purchased from others. Except as specifically admitted, Dart denies the averments contained in paragraph 8 of the Complaint.

8. Dart is without knowledge or information sufficient to form a belief as to the truth of the averments contained in paragraph 9 of the Complaint and therefore Dart denies those averments.

9. Dart denies the averments contained in paragraphs 10 through 13 of the Complaint.

10. In response to the averments contained in paragraph 14 of the Complaint, Dart hereby incorporates by reference its responses to paragraphs 1 through 13.

11. Dart denies the averments contained in paragraphs 15 through 18 of the Complaint.

12. In response to the averments contained in paragraph 19 of the Complaint, Dart hereby incorporates by reference its responses to paragraphs 1 through 18.

13. Dart denies the averments contained in paragraphs 20 through 23 of the Complaint.

14. The Complaint does not contain a paragraph 24; therefore no response is required from Dart.

15. Dart denies the averments contained in paragraph 25 of the Complaint.

16. In response to the averments contained in paragraph 26 of the Complaint, Dart hereby incorporates by reference its responses to paragraphs 1 through 25.

17. In response to the averments contained in paragraph 27 of the Complaint, Dart is without knowledge or information sufficient to form a belief as to the truth of the averment that Anthony Cutone is the husband of Kimberly Cutone and therefore Dart denies that averment. Dart denies the remaining averments contained in paragraph 27 of the Complaint.

18. All averments contained in the Complaint that are not admitted specifically above, are hereby denied.

**AS AND FOR AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

19. Plaintiffs' alleged causes of action contained in the Complaint may be barred by applicable statutes of limitation or by the doctrine of laches.

**SECOND AFFIRMATIVE DEFENSE**

20. Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

**THIRD AFFIRMATIVE DEFENSE**

21. If the causes of action asserted in plaintiffs' Complaint state claims upon which relief can be granted, plaintiffs have failed to join and include in this action all identifiable and indispensable parties without whom in equity and in fairness this action should not proceed.

**FOURTH AFFIRMATIVE DEFENSE**

22. To the extent that plaintiffs assert claims of fraud, plaintiffs have failed to state a cause of action in that plaintiffs assert mere allegations and fail to state with particularity the circumstances constituting the wrong as required by

Rule 9 of the Rules of the Superior Court for the District of Columbia for Civil Cases.

FIFTH AFFIRMATIVE DEFENSE

23. Plaintiffs lack capacity and standing to sue by reason of the fact that no duty was owed the plaintiffs by this answering defendant at the time the mother of the plaintiff Kimberly Cutone allegedly used the drug referred to in the Complaint or by the reason of the doctrine of en ventre sa mere and, therefore, plaintiffs have failed to state facts sufficient to state a claim upon which relief can be granted.

SIXTH AFFIRMATIVE DEFENSE

24. The plaintiffs have been unable to identify this defendant as the defendant causing the alleged injuries, and therefore have failed to state a cause of action against this defendant.

SEVENTH AFFIRMATIVE DEFENSE

25. Any damages, injuries or losses that may have been sustained by the plaintiffs, as alleged in the Complaint, were sustained only after the mother of the plaintiff Kimberly Cutone knowingly and voluntarily assumed any alleged risk inherent in the consumption or use of the drug referred to in the Complaint, with respect to herself and her offspring.

EIGHTH AFFIRMATIVE DEFENSE

26 Upon information and belief, any injuries, losses or damages that the plaintiffs may have sustained were caused by the negligence of the plaintiffs.

NINTH AFFIRMATIVE DEFENSE

27. Plaintiffs are barred from asserting the claims contained in the Complaint because if the drug referred to in the Complaint was used by the mother of the plaintiff Kimberly Cutone during her pregnancy with the plaintiff Kimberly Cutone, the use of said drug was responsible for the birth of the plaintiff Kimberly Cutone.

TENTH AFFIRMATIVE DEFENSE

28. If the plaintiffs sustained any injury or incurred any loss or damage as alleged in the Complaint, the same were caused in whole or in part by acts or omissions of another or others over whom this defendant exercised and had no right of control, for which this defendant is not responsible, and whose conduct this defendant had no duty or reason to anticipate or control.

ELEVENTH AFFIRMATIVE DEFENSE

29. If in fact the mother of the plaintiff Kimberly Cutone used the product referred to in the Complaint, upon information and belief, said product was used for a purpose and in a manner not intended or recommended by the manufacturer or distributor thereof and over which this defendant had no control.

TWELFTH AFFIRMATIVE DEFENSE

30. With respect to all claims based upon alleged breach of express or implied warranties, there was no privity between the plaintiffs and this defendant.

THIRTEENTH AFFIRMATIVE DEFENSE

31. With respect to all claims based upon alleged breach of express or implied warranties, there was no timely notice of any alleged breach of warranty given to this defendant at any time.

FOURTEENTH AFFIRMATIVE DEFENSE

32. The causes of action asserted herein by the plaintiffs, who admittedly are unable to identify the manufacturer of the alleged injury-causing product, fail to state a claim upon which relief can be granted, in that, inter alia, plaintiffs have asserted claims for relief which, if granted, would contravene this defendant's constitutional rights to substantive and procedural due process of law under the United States Constitution.

FIFTEENTH AFFIRMATIVE DEFENSE

33. The causes of action asserted by the plaintiffs herein, who admittedly are unable to identify the manufacturer of the alleged injury-causing product, fail to state a claim upon which relief can be granted, in that, inter alia, plaintiffs have asserted claims for relief, which, if granted, would constitute a taking of private property for a public use, without just compensation and such a taking would contravene this defendant's constitutional rights under the United States Constitution.

SIXTEEN TH AFFIRMATIVE DEFENSE

34. The causes of action asserted herein by the plaintiffs fail to state a claim upon which relief can be granted, in that, inter alia, plaintiffs have asserted claims for relief which, if granted, would constitute a denial by this Court of this

defendant's constitutional rights to equal protection of the laws under the United States Constitution.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

35. The causes of action asserted herein by the plaintiffs fail to state a claim upon which relief can be granted in that, inter alia, plaintiffs have asserted claims for relief, which, if granted, would impose an improper, retroactive penalty and impermissible intrusion on interstate commerce and federal laws and regulations and would, thereby, violate the United States Constitution.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

36. If in fact plaintiffs' Complaint were held to contain a cause of action upon which relief could be granted, then plaintiffs' recovery, if any, should be reduced by the relative amount of comparative fault attributable to the plaintiffs, or their agents, or persons other than this answering defendant.

**NINETEENTH AFFIRMATIVE DEFENSE**

37. The place of filing of this action was set without due regard to the convenience of the parties, witnesses, feasibility of compelling testimony of witnesses, availability of physical evidence or other proof and constitutes a forum non conveniens that requires that the action be tried in another jurisdiction.

**TWENTIETH AFFIRMATIVE DEFENSE**

38. Plaintiffs' demand for punitive damages is barred by the following clauses to the United States Constitution: the due process clauses of the Fourteenth Amendment; the double jeopardy clause of the Fifth Amendment; and the ex post facto clause of Article 1, section 10.

TWENTY FIRST AFFIRMATIVE DEFENSE

39. Dart incorporates by reference and makes a part hereof all applicable affirmative defenses set forth in the answers of any other defendant and will rely on all defenses which may become available during discovery or trial.

**WHEREFORE**, Defendant Dart Industries, Inc. respectfully prays that this Court dismiss the Complaint herein or otherwise deny each and every request for relief therein and that it be awarded such other and further relief to which it may be entitled and which this Court may deem just and proper, including the costs and disbursements of the defense of this action.

DART INDUSTRIES, INC.

By Counsel

Troutman Sanders LLP  
1660 International Drive, Suite 600  
McLean, Virginia 22102  
(703) 734-4356

By:

  
John F. Anderson  
DC Bar No. 393764

OF COUNSEL

Sheila AnnMarie Moeller  
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31 Brookside Drive  
Greenwich, CT 06836  
(203) 622-9360

**CERTIFICATE OF SERVICE**

I hereby certify that on this 22<sup>nd</sup> day of July 2004 a copy of the foregoing was served by first class mail on the following:

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Sidney Gordon Leech  
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Eccleston & Wolf  
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Drinker, Biddle & Reath  
1500 K Street, N.W., Suite 1100  
Washington, D.C. 20005

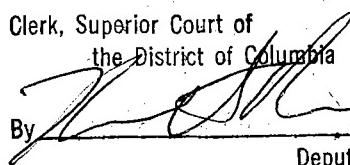


John F. Anderson

A TRUE COPY

TEST: **AUG 9 2004**

Clerk, Superior Court of  
the District of Columbia



By

Deputy Clerk

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
Civil Division

KIMBERLY C. CUTONE, et vir.

Plaintiffs

v.

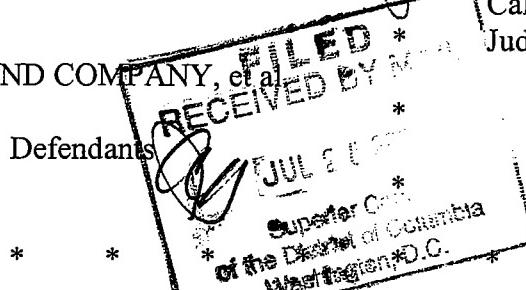
ELI LILLY AND COMPANY, et al.

Defendants

Civil Action No.: 04-CA-005307

Calendar No.: 2

Judge Michael L. Rankin



**BRISTOL-MYERS SQUIBB COMPANY'S ANSWER TO COMPLAINT**

Bristol-Myers Squibb Company, one of the Defendants, by its attorneys, Sidney G. Leech, Malcolm S. Brisker, and GOODELL, DEVRIES, LEECH & DANN, LLP, for an Answer to the Complaint filed against it by the Plaintiffs in the above-captioned case says:

**FIRST DEFENSE**

That the Complaint fails to state a claim against this Defendant upon which relief can be granted.

**SECOND DEFENSE**

1. As to Paragraph 1 of the Complaint, this Defendant lacks sufficient information to form a belief as to the truth of the allegations contained in this paragraph and, therefore, can neither admit nor deny the allegations in this paragraph and demands strict proof thereof by the Plaintiffs.

2. As to Paragraph 2 of the Complaint, this Defendant admits that it is engaged in the manufacturing, marketing, sale, promotion, and distribution of

pharmaceuticals throughout the United States, and admits it is doing business in the District of Columbia, but denies the remainder of this paragraph as phrased.

3. As to Count I, Paragraphs 3, 4 and 5 of the Complaint, this Defendant denies the allegations of these paragraphs as to it.

4. As to Count II, Paragraph 6 of the Complaint, this Defendant incorporates by reference its prior responses to Paragraphs 1 through 5 as fully as if they were repeated verbatim herein.

5. As to Count II, Paragraphs 7, 9, 10, 11, 12, and 13 of the Complaint, this Defendant denies the allegations of these paragraphs as to it.

6. As to Count II, Paragraph 8 of the Complaint, this Defendant admits that its predecessor previously manufactured DES, but denies all further allegations of this paragraph as phrased.

7. As to Count III, Paragraph 14 of the Complaint, this Defendant incorporates by reference its prior responses to paragraphs 1 through 13 as fully as if they were repeated verbatim herein.

8. As to Count III, Paragraphs 15, 16, 17, and 18 of the Complaint, this Defendant denies the allegations of these paragraphs as to it.

9. As to Count IV, Paragraph 19 of the Complaint, this Defendant incorporates by reference its prior responses to Paragraphs 1 through 18 as fully as if they were repeated verbatim herein.

10. As to Count IV, Paragraphs 20, 21, 22, and 23 of the Complaint, this Defendant denies the allegations of these paragraphs as to it.

11. As to Count V, Paragraph 25 of the Complaint, this Defendant denies the allegations of this paragraph as to it.

12. As to Count VI, Paragraph 26 of the Complaint, this Defendant incorporates by reference its prior responses to Paragraphs 1 through 25 as fully as if they were repeated verbatim herein.

13. As to Count VI, Paragraph 27 of the Complaint, this Defendant denies the allegations of this paragraph as to it.

**AFFIRMATIVE AND OTHER DEFENSES**

**FIRST DEFENSE**

This Defendant denies any allegation contained in Plaintiff's Complaint in the above-captioned case to which this Defendant has not specifically responded.

**SECOND DEFENSE**

Plaintiff's causes of action are barred by the applicable statute or statutes of limitation.

**THIRD DEFENSE**

Plaintiff's natural mother was guilty of contributory negligence which was a proximate cause of the injuries, damages and losses complained of, which negligence is a complete bar to the recovery by Plaintiff in this case.

**FOURTH DEFENSE**

Plaintiff's natural mother assumed the risks inherent in the use of Diethylstilbestrol and her assumption of risk is a bar to Plaintiff's recovery in this case.

**FIFTH DEFENSE**

Plaintiff's natural mother misused or abused Diethylstilbestrol, which she consumed or ingested, which conduct is a complete bar to Plaintiff's recovery in this case.

**SIXTH DEFENSE**

If Plaintiff sustained any of the injuries as alleged in the Complaint, which is hereby expressly denied, there was an intervening cause and/or causes leading to said alleged injuries and, as such, any action on the part of this Defendant was not the proximate cause of Plaintiff's alleged injuries.

**SEVENTH DEFENSE**

If Plaintiff sustained any of the injuries as alleged in the Complaint, which is hereby expressly denied, said injuries were caused in whole or in part by the conduct of one or more third persons for whose conduct this Defendant is not responsible or with whom this Defendant had no legal relationship.

**EIGHTH DEFENSE**

This Complaint is barred in whole or in part by the application statute or statutes of repose.

**NINTH DEFENSE**

The Complaint fails to join a necessary party or parties without whom complete relief cannot be granted.

**TENTH DEFENSE**

If the product in question was unsafe, then it was unavoidably unsafe.

**ELEVENTH DEFENSE**

The Plaintiff's causes of action are barred by the doctrine of res judicata or the doctrine of collateral estoppel.

**TWELFTH DEFENSE**

If this Defendant's product was ingested by Plaintiff's natural mother, then this Defendant alleges that such product was in conformity with the generally recognized state-of-the-art at the time it was designed, manufactured, inspected, packaged, labeled and sold; therefore, Plaintiff is barred from recovery.

**THIRTEENTH DEFENSE**

Plaintiff's causes of action are barred by the Doctrine of Laches.

**FOURTEENTH DEFENSE**

All of Plaintiff's causes of action are barred by the Doctrine of Federal Preemption.

**FIFTEENTH DEFENSE**

At all applicable times, this Defendant fully complied with all applicable Federal, State, and local statutory and regulatory requirements concerning DES, including those prescribed by the federal Food, Drug and Cosmetic Act and those promulgated by the federal Food and Drug Administration.

**SIXTEENTH DEFENSE**

The Plaintiff is barred from recovery in the above-captioned case based on the application of the learned intermediary doctrine.

**SEVENTEENTH DEFENSE**

This Defendant states there are no allegations contained in the Complaint legally sufficient to support a cause of action for exemplary or punitive damages as to this Defendant and, therefore, all claims for punitive or exemplary damages in the above-captioned case should be dismissed with prejudice.

**EIGHTEENTH DEFENSE**

Any claims in the Complaint that seek an award of exemplary or punitive damages violate this Defendant's right to procedural due process as provided in the Fifth and Fourteenth Amendments of the United States Constitution.

**NINETEENTH DEFENSE**

Any claims in the Complaint that seek an award of exemplary or punitive damages violate this Defendant's right to substantive due process as provided in the Fifth and Fourteenth Amendments of the United States Constitution.

**TWENTIETH DEFENSE**

Any claims in the Complaint that seek an award of exemplary or punitive damages would violate this Defendant's right to protection from "excessive fines" as provided in the Eighth Amendment of the United States Constitution.

**TWENTY-FIRST DEFENSE**

Count V of the Complaint does not constitute a separate cause of action, but is merely a request for a different type of damages and, therefore, Count V of the Complaint is a legal nullity.

**TWENTY-SECOND DEFENSE**

Any claims in the Complaint that seek an award of exemplary or punitive damages would violate this Defendant's right to equal protection under the law and are otherwise unconstitutional under the Fourteenth Amendment of the United States Constitution.

**TWENTY-THIRD DEFENSE**

Count VI of the Complaint is legally insufficient because the cause of action is a joint one in which both husband and wife must join, and because at the time of the alleged injuries, the Plaintiffs were not husband and wife and, therefore, they are not entitled to maintain a cause of action for loss of consortium.

**WHEREFORE**, Bristol-Myers Squibb Company, one of the Defendants, moves this Honorable Court to enter an Order in the above-captioned case dismissing the Complaint with prejudice as to it, or for such other and further relief as may be appropriate under the circumstances.

  
Sidney G. Leech (D.C. Bar No. 359071)

Malcolm S. Brisker  
Goodell, DeVries, Leech & Dann, LLP  
One South Street, 20<sup>th</sup> Floor  
Baltimore, Maryland 21202  
410-783-4000

*Atorneys for Defendant,  
Bristol-Myers Squibb Company*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 26 <sup>th</sup> day of July, 2004, a copy of Defendant Bristol-Myers Squibb Company's Answer to Complaint was mailed via first class mail, postage-prepaid to:

Aaron M. Levine, Esquire  
Aaron M. Levine & Associates, P.A.  
1320 19<sup>th</sup> Street, N.W., Suite 500  
Washington, D.C. 20036; *Attorney for Plaintiffs*

Lawrence H. Martin, Esquire  
Foley Hoag, LLP  
1747 Pennsylvania Avenue, N.W.  
Washington, D.C. 20006

James J. Dillon, Esquire  
Foley Hoag LLP  
155 Seaport Boulevard  
Boston, MA 02210; *Attorneys for Eli Lilly and Company*

John F. Anderson, Esquire  
Troutman Sanders, LLP  
1660 International Drive  
Suite 600, Tysons Corner  
McLean, VA 22102; *Attorneys for Dart Industries, Inc.*

Aaron L. Handleman, Esquire  
Eccelston & Wolf, P.C.  
2001 S Street, Suite 310  
Washington, D.C. 20009; *Attorneys for Premo Pharmaceutical Laboratories, Inc.*

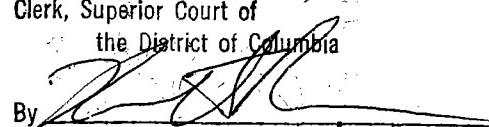
Michael J. McManus, Esquire  
Elizabeth Ewert, Esquire  
Drinker, Biddle and Reath  
1500 K Street, NW  
Suite 1100  
Washington, DC 20005-1209; *Attorneys for Pharmacia and Upjohn Company*

Wyeth-Ayerst Laboratories  
Post Office Box 8299  
Philadelphia, PA 19101



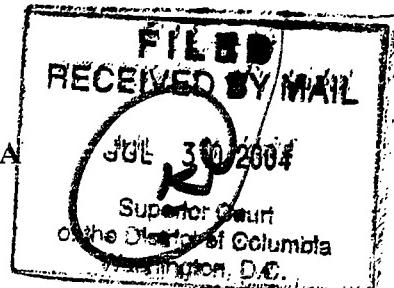
Sidney G. Leech

A TRUE COPY	
TEST:	AUG 9 2004
Clerk, Superior Court of the District of Columbia	
By	Deputy Clerk



SUPERIOR COURT OF THE DISTRICT OF COLUMBIA

Civil Division



KIMBERLY CUTONE, et al.,

Plaintiffs,

v.

ELI LILLY AND COMPANY, et al.,

Defendant

Civil Action No. 04-005307  
Calendar #2  
Judge Michael L. Rankin

PLAINTIFF'S PROOF OF SERVICE

I, BRANDON J. LEVINE, being duly sworn deposes and states:

1. That I am attorney of record for the Plaintiffs, Kimberly and Anthony Cutone, in the above cause.
2. That on July 13, 2004 I personally caused to be mailed, certified mail, return receipt requested, the Complaint, Summons, and Initial Order to Pharmacia and Upjohn Company, Defendant in this action. That on July 14, 2004, said Complaint, Summons, and Initial Order, was served on the Defendant, as shown by the return receipt, attached hereto.

I declare under the penalty of perjury that the foregoing is true and correct.

AARON M. LEVINE & ASSOCIATES

Brandon J. Levine #412130  
1320 19<sup>th</sup> Street, N.W., Suite 500  
Washington, D.C. 20036  
202/833 - 8040

Counsel for Plaintiff

Sworn to before me, this 28<sup>th</sup> day of July, 2004.

Chen Rosling,  
Notary Public  
Commission Expires:  
5/31/09

SUPERIOR COURT OF THE DISTRICT OF COLUMBIA

Civil Division

KIMBERLY CUTONE, et al.,	]	
	]	
Plaintiffs,	]	Civil Action No. 04-005307
	]	Calendar #2
v.	]	Judge Michael L. Rankin
	]	
ELI LILLY AND COMPANY, et al.,	]	
	]	
Defendant	]	

**PLAINTIFF'S PROOF OF SERVICE**

I, BRANDON J. LEVINE, being duly sworn deposes and states:

1. That I am attorney of record for the Plaintiffs, Kimberly and Anthony Cutone, in the above cause.
2. That on July 13, 2004 I personally caused to be mailed, certified mail, return receipt requested, the Complaint, Summons, and Initial Order to Eli Lilly and Company, Defendant in this action. That on July 14, 2004, said Complaint, Summons, and Initial Order, was served on the Defendant, as shown by the return receipt, attached hereto.

I declare under the penalty of perjury that the foregoing is true and correct.

AARON M. LEVINE & ASSOCIATES

Brandon J. Levine #412130  
1320 19<sup>th</sup> Street, N.W., Suite 500  
Washington, D.C. 20036  
202/833 - 8040

Counsel for Plaintiff

Sworn to before me, this 28 day of July, 2004.

Cherry Parry,  
Notary Public  
Commission Expires: 5/31/09

SUPERIOR COURT OF THE DISTRICT OF COLUMBIA

Civil Division

KIMBERLY CUTONE, et al.,	]	
	]	
Plaintiffs,	]	Civil Action No. 04-005307
	]	Calendar #2
v.	]	Judge Michael L. Rankin
	]	
ELI LILLY AND COMPANY, et al.,	]	
	]	
Defendant	]	

**PLAINTIFF'S PROOF OF SERVICE**

I, BRANDON J. LEVINE, being duly sworn deposes and states:

1. That I am attorney of record for the Plaintiffs, Kimberly and Anthony Cutone, in the above cause.
2. That on July 13, 2004 I personally caused to be mailed, certified mail, return receipt requested, the Complaint, Summons, and Initial Order to Premo Pharmaceutical Laboratories, Inc., Defendant in this action. That on July 15, 2004 said Complaint, Summons, and Initial Order, was served on the Defendant, as shown by the return receipt, attached hereto.

I declare under the penalty of perjury that the foregoing is true and correct.

AARON M. LEVINE & ASSOCIATES

Brandon J. Levine #412130  
1320 19<sup>th</sup> Street, N.W., Suite 500  
Washington, D.C. 20036  
202/833 - 8040

Counsel for Plaintiff

Sworn to before me, this 25<sup>th</sup> day of July, 2004.

Charles Morris,  
Notary Public  
Commission Expires: 5/31/09

SUPERIOR COURT OF THE DISTRICT OF COLUMBIA

Civil Division

KIMBERLY CUTONE, et al.,	]	
	]	
Plaintiffs,	]	Civil Action No. 04-005307
	]	Calendar #2
v.	]	Judge Michael L. Rankin
	]	
ELI LILLY AND COMPANY, et al.,	]	
	]	
Defendant	]	

PLAINTIFF'S PROOF OF SERVICE

I, BRANDON J. LEVINE, being duly sworn deposes and states:

1. That I am attorney of record for the Plaintiffs, Kimberly and Anthony Cutone, in the above cause.
2. That on July 13, 2004 I personally caused to be mailed, certified mail, return receipt requested, the Complaint, Summons, and Initial Order to Wyeth-Ayerst Laboratories, Defendant in this action. That said Complaint, Summons, and Initial Order, was served on the Defendant, as shown by the return receipt, attached hereto.

I declare under the penalty of perjury that the foregoing is true and correct.

AARON M. LEVINE & ASSOCIATES

Brandon J. Levine #412130  
1320 19<sup>th</sup> Street, N.W., Suite 500  
Washington, D.C. 20036  
202/833 - 8040

~~Counsel for Plaintiff~~

A TRUE COPY  
TEST: AUG 9 2004

Clerk, Superior Court of  
the District of Columbia

By

Deputy Clerk

Sworn to before me, this 25 day of July, 2004.

Charles R. Levy,  
Notary Public  
Commission Expires:

5/31/09

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
Civil Division

KIMBERLY C. CUTONE, and ANTHONY  
CUTONE  
54 Gould Street  
West Roxbury, MA 02132

Plaintiffs,

v.

ELI LILLY AND COMPANY  
Lilly Corporate Center  
Indianapolis, IN 46285

w/s/o NATIONAL REGISTERED AGENTS, INC.  
1090 Vermont Avenue, NW, # 910  
Washington, DC 20005

and

BRISTOL-MYERS SQUIBB COMPANY  
a successor of E.R. SQUIBB & SONS, INC.  
P.O. Box 4500  
Princeton, NJ 08543

w/s/o CT CORPORATION  
1025 Vermont Avenue, N.W.  
Washington, D.C. 20005

Civil Action No. 04-0005307

and

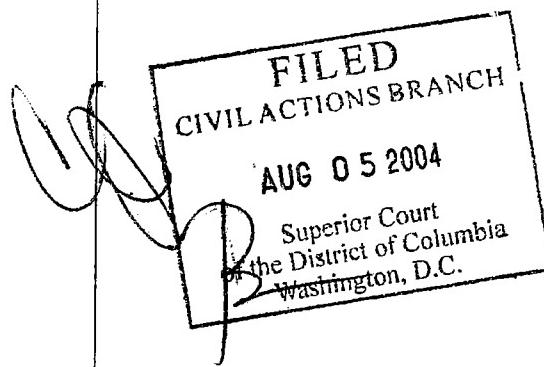
PHARMACIA and UPJOHN COMPANY  
(aka THE UPJOHN COMPANY)  
100 Route 206 North  
Peapack, NJ 07977

w/s/o CT CORPORATION  
1025 Vermont Avenue, N.W.  
Washington, D.C. 20005

and

DART INDUSTRIES, INC., a successor to  
REXALL DRUG COMPANY, INC.  
14901 South Orange Blossom Trail  
Orlando, FL 32837

w/s/o Sheila AnnMarie Moeller, Esq.  
Gilbride, Tusa, Last & Spellane, LLC  
31 Brookside Drive  
Greenwich, CT 06836



and

**PREMO PHARMACEUTICAL  
LABORATORIES, INC.**

w/s/o Corporation Trust Co.  
820 Bear Tavern Road  
West Trenton, NJ 08628

and

**WYETH-AYERST LABORATORIES**  
P.O. Box 8299  
Philadelphia, PA 19101

Defendants.

**WYETH'S ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Wyeth, on behalf of itself and its unincorporated division Wyeth Pharmaceuticals,<sup>1</sup> answers the Complaint of plaintiffs Kimberly C. Cutone and Anthony Cutone ("Complaint") as follows: Wyeth denies each allegation in the Complaint except those expressly admitted below. Wyeth also states that, to the extent that allegations in the Complaint refer generally to "defendants," Wyeth answers the allegations as to itself. To the extent that allegations in the Complaint refer to defendants other than Wyeth, Wyeth states that it lacks knowledge sufficient to form a belief as to the truth of the allegations and, therefore, denies the allegations.

1. Paragraph 1 states a legal conclusion that requires no response. Should a response be required, Wyeth denies the allegation in paragraph 1 of the Complaint.

2. Wyeth admits that it manufactures, markets, and distributes certain pharmaceuticals. Wyeth further admits that Ayerst, McKenna & Harrison, Ltd., a company later

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<sup>1</sup> Wyeth-Ayerst Laboratories, the named defendant, was an unincorporated division of American Home Products Corporation. American Home Products Corporation changed its name to Wyeth on March 11, 2002. The division formerly known as Wyeth-Ayerst Laboratories is now known as Wyeth Pharmaceuticals.

acquired by Wyeth, sought and obtained approval from the United States Food & Drug Administration for diethylstilbestrol ("DES"). Wyeth denies the remaining allegations in paragraph 2 of the Complaint.

**COUNT I**  
**(Negligence)**

3. Wyeth lacks knowledge sufficient to form a belief as to the truth of the allegations in the first two sentences and the last sentence of paragraph 3 and, therefore, denies the allegations. Wyeth admits that, at times in the past, it manufactured, supplied, and sold DES. Wyeth denies the remaining allegations in paragraph 3 of the Complaint, including any allegation that Wyeth manufactured the DES to which plaintiff Kimberly Cutone was exposed.

4. Wyeth denies the allegations in paragraph 4 of the Complaint.
5. Wyeth denies the allegations in paragraph 5 of the Complaint.

**COUNT II**  
**(Strict Liability)**

6. Wyeth incorporates and realleges the answers to the preceding paragraphs as if fully set forth herein.

7. Wyeth denies the allegations in paragraph 7 of the Complaint.  
8. Wyeth admits that, at times in the past, it manufactured DES. Wyeth denies the remaining allegations in paragraph 8 of the Complaint, including any allegation that Wyeth manufactured the DES to which plaintiff Kimberly Cutone was exposed.

9. Wyeth lacks knowledge sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Complaint and, therefore, denies the allegations.  
10. Wyeth denies the allegations in paragraph 10 of the Complaint.  
11. Wyeth denies the allegations in paragraph 11 of the Complaint.

12. Wyeth denies the allegations in paragraph 12 of the Complaint.
13. Wyeth denies the allegations in paragraph 13 of the Complaint.

**COUNT III**  
**(Breach of Warranty)**

14. Wyeth incorporates and realleges the answers to the preceding paragraphs as if fully set forth herein.
15. Wyeth denies the allegations in paragraph 15 of the Complaint.
16. Wyeth denies the allegations in paragraph 16 of the Complaint.
17. Wyeth denies the allegations in paragraph 17 of the Complaint.
18. Wyeth denies the allegations in paragraph 18 of the Complaint.

**COUNT IV**  
**(Misrepresentation)**

19. Wyeth incorporates and realleges the answers to the preceding paragraphs as if fully set forth herein.
20. Wyeth denies the allegations in paragraph 20 of the Complaint.
21. Wyeth lacks knowledge sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint and, therefore, denies the allegations.
22. Wyeth denies the allegations in paragraph 22 of the Complaint.
23. Wyeth denies the allegations in paragraph 23 of the Complaint.

**COUNT V**  
**(Punitive Damages)**

24. There is no paragraph 24 of the Complaint
25. Wyeth denies the allegations in paragraph 25 of the Complaint.

**COUNT VI**  
**(Loss of Consortium – Anthony Cutone)**

26. Wyeth incorporates and realleges the answers to the preceding paragraphs as if fully set forth herein.

27. Wyeth lacks knowledge sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 27 and, therefore, denies the allegations. Wyeth denies the remaining allegations in paragraph 27 of the Complaint.

Wyeth admits that plaintiffs seek the relief requested in the "WHEREFORE" paragraphs immediately following paragraph 27 of the Complaint, but denies that plaintiffs are entitled to the relief requested or any relief whatsoever.

**AFFIRMATIVE DEFENSES**

As for additional defenses to the Complaint, and without assuming any burden of pleading or proof that would otherwise rest on plaintiffs, Wyeth alleges as follows:

**First Affirmative Defense**

The Complaint fails to state, in whole or in part, a claim upon which relief may be granted.

**Second Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose.

**Third Affirmative Defense**

Plaintiff Kimberly Cutone's natural mother knowingly and voluntarily assumed any and all risks associated with the matters alleged in the Complaint. Pursuant to the doctrines of assumption of the risk or informed consent, this conduct bars in whole or in part the damages that plaintiffs seek to recover herein.

**Fourth Affirmative Defense**

Plaintiffs' claims are barred because the injuries allegedly sustained by plaintiffs were not proximately caused by any act or omission of Wyeth.

**Fifth Affirmative Defense**

Plaintiffs' recovery, if any, should be reduced pursuant to the comparative negligence, fault, responsibility, or causation of others.

**Sixth Affirmative Defense**

If plaintiff was injured by any product manufactured, sold, or distributed by Wyeth, those injuries occurred because the product was used for a purpose other than that for which it was intended, in a manner other than that in which it was intended to be used, and in disregard of instructions and directions regarding its use. Such misuse was not reasonably foreseeable to Wyeth.

**Seventh Affirmative Defense**

Plaintiffs' alleged injuries and damages, if any, were caused in whole or in part by the acts and omissions of third parties over whom Wyeth had no authority or control, including without limitation, misuse of diethylstilbestrol (the "subject product") by such third parties.

**Eighth Affirmative Defense**

Plaintiffs' claims are barred because any injuries and damages allegedly sustained by plaintiffs were the result of pre-existing or subsequent conditions that are unrelated to use of the subject product.

**Ninth Affirmative Defense**

Plaintiffs' claims are barred because any injuries and damages allegedly sustained by plaintiffs were the direct and proximate result of an independent, unforeseeable, superseding, or intervening cause.

**Tenth Affirmative Defense**

Plaintiffs' claims are barred because any injuries and damages allegedly sustained by plaintiffs as a result of the subject product were caused by an idiosyncratic reaction to the subject product that was not reasonably foreseeable to Wyeth.

**Eleventh Affirmative Defense**

Plaintiffs' claims are barred by reason of plaintiffs' failure to mitigate the alleged damages or losses.

**Twelfth Affirmative Defense**

Plaintiffs' claims are barred by the equitable doctrines of laches, waiver, and estoppel.

**Thirteenth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the doctrines of merger, bar, collateral estoppel, res judicata, release, discharge, and accord and satisfaction.

**Fourteenth Affirmative Defense**

Wyeth denies, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of Wyeth, or at the instruction or subject to the control of Wyeth with regard to any of the actions described in the Complaint; thus, Wyeth is not liable for any acts or omissions of such third parties as a matter of law.

**Fifteenth Affirmative Defense**

Wyeth avers that it did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

**Sixteenth Affirmative Defense**

Wyeth affirmatively pleads the application of comment k of section 402A of the Restatement (Second) of Torts and section 6(c) of the Restatement (Third) of Torts: Product Liability and its limitations upon the doctrine of strict product liability for purported design defect.

**Seventeenth Affirmative Defense**

Plaintiffs' claims based on Wyeth's alleged duty to warn are barred by the learned intermediary doctrine.

**Eighteenth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the lack of a defect since the subject product was properly prepared in accordance with the applicable standard of care.

**Nineteenth Affirmative Defense**

Plaintiffs' claims are barred because, based on the state of scientific, medical and technical knowledge at the time the subject product was marketed, the product was reasonably safe for its normal and foreseeable use at all times, it was not unreasonably dangerous or defective, and its benefits exceeded any associated risks.

**Twentieth Affirmative Defense**

Plaintiffs' claims are barred because the methods, standards, and techniques utilized by Wyeth in manufacturing, distributing, marketing, or labeling the subject product and in issuing warnings and instructions with respect to its use, conformed with the generally recognized,

reasonably available, and reliable state of knowledge at the time the drug was manufactured and distributed.

**Twenty-First Affirmative Defense**

Plaintiffs' claims predicated on state tort law and alleging that the subject product is unsafe are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

**Twenty-Second Affirmative Defense**

The conduct of Wyeth, as well as the subject product, conformed with the Federal Food, Drug, and Cosmetic Act and the requirements of the Food and Drug Administration. Moreover, the activities of Wyeth alleged in the Complaint conformed with all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Complaint.

**Twenty-Third Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because Wyeth's advertisements and labeling with respect to the subject product were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Twenty-Fourth Affirmative Defense**

To the extent plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Wyeth's rights under the United States Constitution.

**Twenty-Fifth Affirmative Defense**

Plaintiff is not entitled to an award of attorneys' fees in the absence of a contract, statute, or law authorizing such fees.

**Twenty-Sixth Affirmative Defense**

Should Wyeth be held liable to plaintiffs, which liability is specifically denied, Wyeth would be entitled to a set off for the total of all amounts paid to plaintiffs from all collateral sources.

**Twenty-Seventh Affirmative Defense**

To the extent applicable, plaintiffs' purported breach of warranty claims are barred by a lack of privity between plaintiffs and Wyeth and because plaintiffs failed to provide Wyeth with reasonable or adequate notice of the alleged breach of any such purported warranties.

**Twenty-Eighth Affirmative Defense**

If plaintiffs are unable to identify and prove the specific manufacturer of the alleged injury-causing product, they fail to state a claim upon which relief can be granted in that they have asserted claims for relief which, if granted, would violate the public policy of the District of Columbia and all other applicable states, and constitute a denial by this Court of Wyeth's federal and state constitutional rights to due process of law, equal protection of the law, and to be free from the imposition of state law liabilities that interfere with the federal regulation of pharmaceutical products and the free flow of commerce between and among the states.

**Twenty-Ninth Affirmative Defense**

If plaintiffs are unable to identify and prove the specific manufacturer of the alleged injury-causing product, they lack standing to pursue this action.

**Thirtieth Affirmative Defense**

If Wyeth is found liable to plaintiffs for any loss allegedly suffered by plaintiffs, such liability shall not exceed Wyeth's equitable share determined in accordance with the relative

- (a) imposition of punitive damages by a jury which
  - (1) is not provided with standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award;
  - (2) is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment;
  - (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, wealth, or state of residence of Wyeth;
  - (4) is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; and
  - (5) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards;
- (b) imposition of such punitive damages, and determination of the amount of an award thereof, where applicable state law is impermissibly vague, imprecise, or inconsistent;
- (c) imposition of such punitive damages, and determination of the amount of an award thereof, without bifurcating the trial and trying all punitive damages issues only if and after the liability of defendants has been found on the merits;
- (d) imposition of such punitive damages, and determination of the amount of an award thereof, based on anything other than Wyeth's conduct in connection with the sale of the product alleged in this litigation, or in any other way subjecting Wyeth to impermissible multiple punishment for the same alleged wrong.

Wyeth requests that plaintiff be denied the relief sought in the Complaint and that Wyeth be dismissed from this action and awarded costs together with any additional relief that the Court deems just and proper. Wyeth reserves the right to supplement its answer and affirmative defenses with additional defenses that become available or apparent during the course of investigation, preparation, or discovery and to amend its answer accordingly.

**DEMAND FOR JURY TRIAL**

Wyeth requests a trial by jury for all claims so triable.

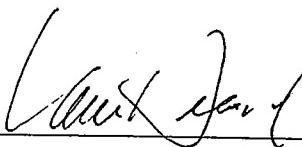
**WHEREFORE**, Wyeth prays for relief and judgment against plaintiff as follows:

- A. That plaintiffs take nothing by reason of the Complaint;
- B. That this action be dismissed with prejudice;
- C. That Wyeth recovers its fees, costs and attorneys' fees incurred herein; and
- D. Such further and other relief as the Court deems proper.

Dated: August 5, 2004.

Respectfully submitted,

WILLIAMS & CONNOLLY LLP

By:   
F. Lane Heard, III (DC Bar No. 291724)

725 12th Street, N.W.  
Washington, D.C. 20005  
(202) 434-5000

Attorneys for Defendant Wyeth

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on August 5, 2004 a true copy of Wyeth's Answer and Affirmative Defenses was served by U.S. First Class Mail, postage prepaid, to the following:

Aaron M. Levine  
AARON M. LEVIN & ASSOCIATES, P.A.  
1320 19<sup>th</sup> Street, N.W.  
Suite 500  
Washington, D.C. 20036  
*Attorneys for Plaintiffs*

Aaron Handleman  
Juli Zsuzsa Simonyi  
ECCLESTON & WOLF, P.C.  
2001 S Street, N.W.  
Suite 310  
Washington, D.C. 20009-1125  
*Attorneys for Premo Pharmaceutical Laboratories, Inc.*

Sidney G. Leech  
GOODELL, DEVRIES, LEECH & DANN,  
LLP  
One South Street  
Suite 2000  
Baltimore, Maryland 21202  
*Attorneys for Bristol-Myers Squibb Company*

Christopher Garvey  
Melanie H. Muhlstock  
GOODWIN PROCTOR LLP  
599 Lexington Avenue  
New York, NY 10022  
*Of Counsel for Premo Pharmaceutical Laboratories, Inc.*

Michael McManus  
Elizabeth Ewert  
DRINKER BIDDLE & REATH  
1500 K Street, N.W., Suite 1100  
Washington, DC 20005-1209  
*Attorneys for Pharmacia and Upjohn Company*

Lawrence Hedrick Martin  
FOLEY HOAG LLP  
1875 K Street, N.W.  
Suite 800  
Washington, D.C. 20006  
*Attorneys for Eli Lilly and Company*

John F. Anderson  
TROUTMAN SANDERS LLP  
1660 International Drive  
Suite 600  
McLean, Virginia 22102  
*Attorneys for Dart Industries, Inc.*

James J. Dillon  
Foley Hoag LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210-2600  
*Attorneys for Eli Lilly Company*

A TRUE COPY  
TEST: **AUG 9 2004**

Clerk, Superior Court of  
the District of Columbia

By

Deputy Clerk

  
F. Lane Heard, III

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
Civil Division

KIMBERLY C. CUTONE, and  
ANTHONY CUTONE,

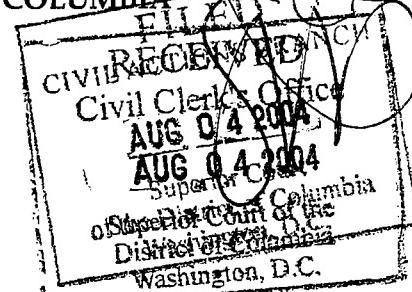
*Plaintiffs,*

v.

ELI LILY AND COMPANY, *et al.*,

*Defendants.*

Civil Action No. 04-005307



**DEFENDANT PHARMACIA & UPJOHN COMPANY'S  
ANSWER TO COMPLAINT**

Defendant Pharmacia & Upjohn Company f/k/a The Upjohn Company ("Upjohn"), by counsel, upon knowledge as to itself and upon information and belief as to all others, answers Plaintiffs Kimberly C. Cutone and Anthony Cutone's Complaint as follows:

1. Upjohn denies that jurisdiction is proper under 11 D.C. Code § 921 (1981 ed.).
2. Upjohn admits that it sells pharmaceutical products and that its predecessor company, at various times sold diethylstilbestrol (DES), which was approved by the Food & Drug Administration. The allegation that Upjohn is "doing business" in the District of Columbia is a legal characterization and/or conclusion to which no response is required. The remainder of the allegations in Paragraph 2 are denied insofar as they are addressed to Upjohn. To the extent that the allegations in Paragraph 2 are directed to other defendants, Upjohn is without knowledge or information sufficient to either admit or deny those allegations; therefore, they are denied.

COUNT I  
(Negligence)

3. Upjohn denies "acting in concert" as alleged. Upjohn admits that its predecessor company at various times sold diethylstilbestrol (DES), which was approved by the Food & Drug Administration. Upjohn is without knowledge or information sufficient to either admit or deny the remaining allegations in Paragraph 3; therefore, those allegations are denied.

4. Upjohn denies the allegations in Paragraph 4.
5. Upjohn denies the allegations in Paragraph 5.

COUNT II  
(Strict Liability)

6. Upjohn incorporates by reference its answers to the allegations in Count I.

7. Upjohn denies the allegations in Paragraph 7.

8. Upjohn denies the allegations in Paragraph 8, except admits that its predecessor company at various times sold diethylstilbestrol (DES), which was approved by the Food and Drug Administration.

9. Upjohn is without knowledge or information sufficient to either admit or deny the allegations in Paragraph 9; therefore, those allegations are denied.

10. Upjohn denies the allegations in Paragraph 10.
11. Upjohn denies the allegations in Paragraph 11.
12. Upjohn denies the allegations in Paragraph 12.
13. Upjohn denies the allegations in Paragraph 13.

COUNT III  
(Breach of Warranty)

14. Upjohn incorporates by reference its answers to the allegations in Counts I and II.

15. Upjohn admits that its predecessor company, at various times sold diethylstilbestrol (DES), which was approved by the Food & Drug Administration. The remainder of the allegations in Paragraph 15 are denied insofar as they are addressed to Upjohn. To the extent that the allegations in Paragraph 15 are directed to other defendants, Upjohn is without knowledge or information sufficient to either admit or deny those allegations; therefore, they are denied.

16. Upjohn denies the allegations in Paragraph 16.

17. Upjohn denies the allegations in Paragraph 17.

18. Upjohn denies the allegations in Paragraph 18.

COUNT IV  
(Misrepresentation)

19. Upjohn incorporates by reference its answers to the allegations in Counts I, II and III.

20. Upjohn denies the allegations in Paragraph 20.

21. Upjohn is without knowledge or information sufficient to either admit or deny the allegations in Paragraph 21; therefore, those allegations are denied.

22. Upjohn denies the allegations in Paragraph 22.

23. Upjohn denies the allegations in Paragraph 23.

COUNT V  
(Punitive Damages)

25. [sic] Upjohn denies the allegations in Paragraph 25.

COUNT VI  
(Loss of Consortium)

26. Upjohn incorporates by reference its answers to the allegations in Counts I, II, III, IV and V.

27. Upjohn denies the allegations in Paragraph 27.

By way of further answer, Upjohn denies all other allegations contained in Plaintiff's Complaint which are not otherwise expressly admitted herein.

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's Complaint is barred by the applicable statutes of limitations, statutes of repose, and/or the doctrine of laches.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's Complaint and any claim for punitive damages are barred by reason of Upjohn's predecessor's compliance with all applicable federal, state, local and regulatory requirements concerning DES.

FOURTH AFFIRMATIVE DEFENSE

Upjohn states that unless its predecessor can be specifically identified as the manufacturer or distributor of the DES allegedly consumed by Plaintiff's mother, any recovery against it would violate its rights under the United States Constitution and the Constitution(s) of the governing state(s), including its right to due process and equal protection.

FIFTH AFFIRMATIVE DEFENSE

Upjohn states that to the extent Plaintiff seeks to recover punitive damages from it, such an award would, if granted, violate its rights to due process and equal protection guaranteed to it under the United States Constitution and the Constitution(s) of the governing state(s).

SIXTH AFFIRMATIVE DEFENSE

Upjohn states that venue is both improper and inconvenient in this judicial district.

SEVENTH AFFIRMATIVE DEFENSE

The Plaintiff's Complaint may be barred by the learned intermediary doctrine.

EIGHTH AFFIRMATIVE DEFENSE

The Plaintiff's Complaint may be barred by the doctrines of contributory negligence, comparative negligence and/or assumption of the risk.

NINTH AFFIRMATIVE DEFENSE

Upjohn states that its predecessor acted at all times in full conformity with the then-existing state of the art.

TENTH AFFIRMATIVE DEFENSE

Upjohn states that plaintiff's breach of warranty claims must fail due to lack of privity and timely notice.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by the doctrine of preemption under the Supremacy Clause of the United States Constitution because DES has been approved as a prescription medical product by the United States Food and Drug Administration ("FDA"), and has been tested, manufactured and labeled in accordance with federal standards and law.

TWELFTH AFFIRMATIVE DEFENSE

All claims raised and all causes of action asserted in the Complaint against Upjohn are barred by the doctrines of estoppel, laches, waiver, or statutory compliance and plaintiff(s) or her natural mother, including contributory negligence, assumption of risk and/or misuse or abuse of such product.

THIRTEENTH AFFIRMATIVE DEFENSE

If plaintiff(s) sustained injuries or incurred expenses as alleged, the same were caused in whole or in part by the conduct of one or more persons or entities for whose conduct Upjohn was not responsible and with whom Upjohn has no legal connection.

FOURTEENTH AFFIRMATIVE DEFENSE

If plaintiff(s) sustained injuries or incurred expenses as alleged, the same were not due or caused by the fault, lack of care, negligence, strict liability, fraud, misrepresentation, or breach of duty on the part of Upjohn.

FIFTEENTH AFFIRMATIVE DEFENSE

If plaintiff(s) sustained injuries or incurred expenses as alleged, the same were caused in whole or in part through the operation of nature, idiosyncratic reaction or other intervening cause or causes.

SIXTEENTH AFFIRMATIVE DEFENSE

If plaintiff(s) sustained injuries or incurred expenses as alleged, the same resulted from the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses of plaintiff(s).

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails to plead fraud and misrepresentation with the particularity required by Federal Rule of Civil Procedures 9(b) and should be dismissed.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff(s) have failed to join as defendants indispensable parties whose Joinder is necessary for this action to proceed.

NINETEENTH AFFIRMATIVE DEFENSE

If plaintiff(s) sustained injury or damage as alleged, they were exacerbated by plaintiff's failure to mitigate such injury or damage.

TWENTIETH AFFIRMATIVE DEFENSE

Any claims based on breach of warranty theory are barred for lack of privity and for failure to give timely notice of any alleged breach of warranty.

TWENTY-FIRST AFFIRMATIVE DEFENSE

This Court lacks subject matter and personal jurisdiction over the claims alleged in plaintiff's Complaint.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Upjohn adopts and incorporates by reference each and every other affirmative defense asserted by any other defendant herein.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Answer to Complaint was sent, via first-class mail, postage prepaid, on this 19<sup>th</sup> day of August, 2004, to:

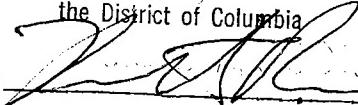
Aaron M. Levine, Esq.  
 Brandon J. Levine, Esq.  
 Renee L. Robinson-Meyer, Esq.  
**AARON M. LEVINE &  
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 1320 - 19<sup>th</sup> Street, N.W.  
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 Charles E. Duross, Esq.  
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 and  
 Lawrence Martin  
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*Attorneys for Eli Lilly and Company*

Sidney Leech, Esq.  
**GOODELL, DEVRIES, LEECH &  
 DANN LLP**

One South Street, 20<sup>th</sup> Floor  
**TRUE COPY**  
 Baltimore, MD 21202 **AUG 9 2004**  
*Attorneys for Bristol-Myers Squibb Co.*  
 Clerk, Superior Court of  
 the District of Columbia

By 

Deputy Clerk

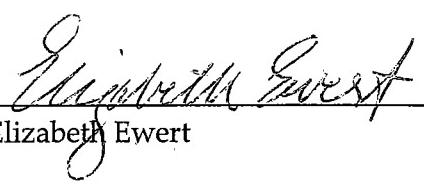
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 Washington, D.C. 20006-2401  
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Carnick Laboratories, Inc.  
 65 Horse Hill Road  
 Cedar Knolls, NJ 07927  
 w/s/o Legal Services Department  
 Morris County Services Office  
 P.O. Box 900  
 Morristown, NJ 07963-0900

  
 Elizabeth Ewert

## IN THE SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA

KIMBERLY C. CUTONE

**FILED**  
CIVIL ACTIONS DIVISION  
AUG 04 2004

Plaintiff, Superior Court  
of the District of Columbia  
Washington, D.C.

2004 AUG -4 P 6:30

ADMINISTRATIVE  
Civil Action No. 04ca5307  
SERVICE DIVISION

v.

ELI LILLY AND CO., et al.

Defendants.

Judge Michael L. Rankin

Calendar No. 2

Next Event: Initial Conference on  
10/15/2004 at 9:30 a.m.

**DEFENDANT PREMO PHARMACEUTICAL LABORATORIES, INC.'S,**  
**ANSWER TO COMPLAINT**

Premo Pharmaceutical Laboratories, Inc., ("Premo") through undersigned counsel, responds as follows to Plaintiff's complaint (the "Complaint"):

In responding to the Complaint, Premo will provide answers only for itself, and will only respond to allegations addressed to or directed at Premo. Premo has no knowledge or information sufficient to form a belief as to the truth or falsity of any allegations relating to any other defendant herein.

1. Denies the allegations in paragraph 1 of the Complaint, and refers all questions of law to the Court.
2. Denies the allegations in paragraph 2 of the Complaint, except admits that at times in the past Premo manufactured and sold DES in dosage form throughout the United States, and that Premo does not contest personal jurisdiction in this matter.

**RESPONDING TO THE FIRST CLAIM FOR RELIEF**

12. Denies the allegations in paragraph 12 of the Complaint.

13. Denies the allegations in paragraph 13 of the Complaint and refers all questions of law to the Court.

---

**RESPONDING TO THE THIRD CLAIM FOR RELIEF**

14. Responding to the allegations in paragraph 14 of the Complaint, Premo repeats and realleges the responses to paragraphs 1 to 13 of the Complaint, *supra*, with the same force and effect as if hereinafter set forth at length.

15. Denies the allegations in paragraph 15 of the Complaint.

16. Denies the allegations in paragraph 16 of the Complaint.

17. Denies the allegations in paragraph 17 of the Complaint.

18. Denies the allegations in paragraph 18 of the Complaint and refers all questions of law to the Court.

**RESPONDING TO THE FOURTH CLAIM FOR RELIEF**

19. Responding to the allegations in paragraph 19 of the Complaint, Premo repeats and realleges the responses to paragraphs 1 to 18 of the Complaint, *supra*, with the same force and effect as if hereinafter set forth at length.

20. Denies the allegations in paragraph 20 of the Complaint, except admits that Premo believed at all times that when it manufactured and sold DES, that DES was safe and effective for its indicated uses.

21. Denies the allegations in paragraph 21 of the Complaint.
22. Denies the allegations in paragraph 22 of the Complaint.
23. Denies the allegations in paragraph 23 of the Complaint and refers all questions of law to the Court.

**RESPONDING TO THE FIFTH CLAIM FOR RELIEF**

24. Responding to the allegations in paragraph 24 of the Complaint, Premo repeats and realleges the responses to paragraphs 1 to 23 of the Complaint, supra, with the same force and effect as if hereinafter set forth at length.

25. Denies the allegations in paragraph 25 of the Complaint.

**RESPONDING TO THE SIXTH CLAIM FOR RELIEF**

26. Responding to the allegations in paragraph 26 of the Complaint, Premo repeats and realleges the responses to paragraphs 1 to 25 of the Complaint, supra, with the same force and effect as if hereinafter set forth at length.

27. Denies the allegations in paragraph 27 of the Complaint.

**FIRST AFFIRMATIVE DEFENSE**

28. The Complaint fails to state a cause of action upon which relief may be granted.

**SECOND AFFIRMATIVE DEFENSE**

29. Plaintiff has failed to join and include in this action all identifiable and indispensable parties without whom, in equity and fairness, this action should not proceed.

**THIRD AFFIRMATIVE DEFENSE**

30. The causes of action alleged in the Complaint are barred by applicable statutes of limitations and by the doctrine of laches.

**FOURTH AFFIRMATIVE DEFENSE**

31. Plaintiff lacks capacity and standing to sue by reason of the fact that no duty was owed the allegedly DES-exposed plaintiff by Premo at the time such plaintiff's mother allegedly used the DES referred to in the Complaint or by reason of the doctrine of *en ventre sa mere*, and therefore, plaintiff has failed to allege facts sufficient to state a cause of action upon which relief may be granted.

**FIFTH AFFIRMATIVE DEFENSE**

32. Plaintiff has been unable to identify Premo as the company causing the alleged injuries, and therefore has failed to state a cause of action against Premo upon which relief may be granted.

**SIXTH AFFIRMATIVE DEFENSE**

33. Any damages, injuries or losses that may have been sustained by plaintiff as alleged in the Complaint were sustained only after the allegedly DES-exposed plaintiff's mother knowingly and voluntarily assumed any alleged risk inherent in the consumption or use of the DES referred to in the Complaint with respect to herself and her offspring.

**SEVENTH AFFIRMATIVE DEFENSE**

34. Upon information and belief, any injuries, losses or damages that plaintiff may have sustained were caused by the allegedly DES-exposed plaintiff's own negligence or that of such plaintiff's mother and, therefore, barred by the doctrine of contributory negligence.

**EIGHTH AFFIRMATIVE DEFENSE**

35. Plaintiff is barred from asserting the causes of action contained in the Complaint because, if the DES referred to in the Complaint was used by the allegedly DES-exposed plaintiff's mother during pregnancy with such plaintiff, the use of said drug was responsible for the birth of such plaintiff.

**NINTH AFFIRMATIVE DEFENSE**

36. If plaintiff sustained any injury or incurred any loss or damages as alleged in the Complaint, the same were caused in whole or in part by acts or omissions of another or others over whom Premo neither exercised nor had any right of control, for which Premo is and was not responsible, and whose conduct Premo had no duty or reason to anticipate or control.

**TENTH AFFIRMATIVE DEFENSE**

37. If in fact the allegedly DES-exposed plaintiff's mother used the DES referred to in the Complaint, upon information and belief, said DES was used for a purpose and in a manner not intended or recommended by the manufacturer or distributor thereof and over which Premo had no control.

**ELEVENTH AFFIRMATIVE DEFENSE**

38. Upon information and belief, if the injuries referred to in the Complaint were caused by a drug manufactured or marketed by Premo, such injuries were the result of an idiosyncratic reaction to such drug by the allegedly DES-exposed plaintiff or by such plaintiff's mother.

**TWELFTH AFFIRMATIVE DEFENSE**

39. With respect to all causes of action based upon alleged breaches of express or implied warranties, there was no privity of contract between plaintiff and Premo.

**THIRTEENTH AFFIRMATIVE DEFENSE**

40. With respect to all causes of action based upon alleged breaches of express or implied warranties, there was no timely notice of any alleged breach of warranty given to Premo at any time.

**FOURTEENTH AFFIRMATIVE DEFENSE**

41. The DES referred to in the Complaint was a prescription drug, and the federal government has preempted the field of law applicable to prescription drug products and their labeling; the manufacture, distribution and sale of the DES referred to in the Complaint were and are controlled by federal law and the manufacture and sale of said drug by Premo at all times were in compliance with applicable federal law; therefore, the Complaint fails to state a cause of action upon which relief may be granted in that, *inter alia*, such claims, if upheld, would impede, impair, frustrate or burden the effectiveness of federal law regulating the field of prescription drugs and would constitute an invalid burden by this Court on interstate commerce, and would,

therefore, violate the Supremacy Clause (Article VI, Section 2) and the Commerce Clause (Article I, Section 8) of the United States Constitution.

**FIFTEENTH AFFIRMATIVE DEFENSE**

42. In view of plaintiff's failure to identify the manufacturer of the alleged injury-causing product, the Complaint fails to state a cause of action upon which relief may be granted, in that, *inter alia*, plaintiff has asserted causes of action which, if granted, would contravene Premo's constitutional rights to substantive and procedural due process of law under both the United States and all applicable state constitutions.

**SIXTEENTH AFFIRMATIVE DEFENSE**

43. In view of plaintiff's failure to identify the manufacturer of the alleged injury-causing product, the Complaint fails to state a cause of action upon which relief may be granted, in that, *inter alia*, plaintiff has asserted causes of action for relief which, if upheld, would constitute a taking of private property for a public use without just compensation and such taking would contravene Premo's constitutional rights under the United States and all applicable state constitutions.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

44. If Premo is found liable to plaintiff for any loss allegedly suffered by plaintiff, such liability shall not exceed Premo's equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

45. If in fact the Complaint is held to contain a cause of action upon which relief may be granted, then plaintiff's recovery, if any, should be reduced by the relative amount of comparative fault attributable to plaintiff or her agents or persons other than Premo or completely barred by the doctrine of contributory negligence.

**NINETEENTH AFFIRMATIVE DEFENSE**

46. If plaintiff sustained the injuries alleged in the Complaint, which is denied, these alleged injuries were caused by factors other than exposure to DES and were not due to caused by the fault, lack of care, negligence or any breach of duty by Premo.

**TWENTIETH AFFIRMATIVE DEFENSE**

47. Plaintiff's claims for relief are barred by the learned intermediary doctrine.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

48. Venue is improper in this Court. In addition, Premo gives notice of its intention to rely upon the doctrine of *forum non conveniens*.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

49. Premo states that to the extent that plaintiff's demand for judgment includes a request for punitive damages, such request is in violation of the Due Process Clause of the Fourteenth Amendment to the United States Constitution and all applicable state constitutions.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

50. Premo states that to the extent that plaintiff's demand for judgment includes a request for punitive damages, such request is in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and all applicable state constitutions.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

51. Any award of punitive damages to plaintiff in this case disproportionate to the actual damages incurred by plaintiff, if any, would be in violation of the constitutional safeguards provided under the Constitution of the United States of America and all applicable state constitutions.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

52. Punitive damages cannot be sustained because of the lack of clarity in the standards for awarding punitive damages and plaintiff has failed to state facts sufficient to support a claim for punitive damages.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

53. Plaintiff's claims are barred by the doctrines of res judicata and/or collateral estoppel and/or waiver.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

54. Premo incorporates by reference herein all other applicable defenses set forth in answers by any other defendants and will rely on all defenses that become available during discovery or trial.

**WHEREFORE**, Premo demands judgment dismissing the Complaint in all respects, for the costs and disbursements of this action, including reasonable attorneys' fees, and for such other and further relief as to this Court may seem just and proper.

ECCLESTON AND WOLF

By

  
Aaron L. Handleman (#48728)

Juli Z. Simonyi (#466921)

Eccleston & Wolf, P.C.

2001 S Street, N.W.

Suite 310

Washington, D.C. 20009

Telephone (202) 857-1696/

Facsimile (202) 857-0762

*Attorney for Defendant,*

*Premo Pharmaceutical Laboratories, Inc.*

Of Counsel:

Christopher Garvey, Esquire

GOODWIN PROCTER LLP

599 Lexington Avenue

New York, New York 10022

(212) 813-8800

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 4<sup>th</sup> day of August, 2004, a copy of the foregoing Answer to Plaintiff's Complaint was faxed and mailed, postage prepared, to:

Aaron M. Levine, Esq.  
Brandon J. Levine, Esq.  
Renee L. Robinson-Meyer, Esq.  
Steven J. Lewis, Esq.  
Aaron M. Levine & Associates, PA  
1320 19<sup>th</sup> Street, NW  
Suite 500  
Washington, DC 20036  
*Attorneys for Plaintiffs*

And sent by regular mail, postage prepared, to:

Lawrence H. Martin, Esquire  
Foley, Hoag, LLP  
1747 Pennsylvania Avenue, NW  
Suite 1200  
Washington, DC 20006-4604

and

James J. Dillon, Esquire  
John Granberry, Esquire  
Foley, Hoag, LLP  
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Washington, DC 20005-1209  
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John F. Anderson, Esquire  
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1660 International Drive  
Suite 600, Tysons Corner  
McLean, Virginia 22102  
*Attorneys for Defendant Dart Industries, Inc.*

and

**PREMO PHARMACEUTICAL  
LABORATORIES, INC.**

w/s/o Corporation Trust Co.  
820 Bear Tavern Road  
West Trenton, NJ 08628

and

**WYETH-A YERST LABORATORIES**  
**P.O. Box 8299**  
**Philadelphia, PA 19101**

Defendants.

**WYETH'S FINANCIAL DISCLOSURE STATEMENT**

Pursuant to Rule 7.1 of the Superior Court Rules of Civil Procedure, defendant Wyeth respectfully submits this Financial Disclosure Statement. Wyeth does not have a parent corporation. No publicly held corporation owns ten percent (10%) or more of Wyeth's stock.

Respectfully submitted,

WILLIAMS & CONNOLLY LLP

By:

  
F. Lane Heard, III (DC Bar No. 291724)

725 12th Street, N.W.  
Washington, D.C. 20005  
(202) 434-5000

Attorneys for Defendant Wyeth

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on August 5, 2004 a true copy of Wyeth's Financial Disclosure Statement was served by U.S. First Class Mail, postage prepaid, to the following:

Aaron M. Levine  
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*Attorneys for Eli Lilly and Company*

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1660 International Drive  
Suite 600  
McLean, Virginia 22102

*Attorneys for Eli Lilly and Company*

TEST: AUG 6 2004

Clerk, Superior Court of  
the District of Columbia

By

Deputy Clerk

James J. Dillon  
Foley Hoag LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210-2600

*Attorneys for Eli Lilly Company*



F. Lane Heard, III

CA Form 1

Superior Court of the District of Columbia  
CIVIL DIVISION

500 Indiana Avenue, N.W., Room JM-170  
Washington, D.C. 20001 Telephone: 879-1133

KIMBERLY C. CUTONE, et al.

0005307-04

*Plaintiff*

vs.

Civil Action No. [redacted]

PREMO PHARMACEUTICAL LABS., INC.

*Defendant*

SUMMONS

To the above named Defendant:

You are hereby summoned and required to serve an Answer to the attached Complaint, either personally or through an attorney, within twenty (20) days after service of this summons upon your exclusive of the day of service. If you are being sued as an officer or agency of the United States Government or the District of Columbia Government you have 60 days after service of this summons to serve your Answer. A copy of the Answer must be mailed to the attorney for the party plaintiff who is suing you. The attorney's name and address appear **below**. If plaintiff has no attorney, a copy of the Answer must be mailed to the plaintiff at the address stated on this Summons.

You are also required to file the original Answer with the Court in Room JM 170 at 500 Indiana Avenue, N.W. between 9:00 am. and 4:00 pm., Mondays through Fridays or between 9:00 am. and 12:00 Noon on Saturdays. You may file the original Answer with the Court either before you serve a copy of the Answer on the plaintiff or within five (5) days after you have served the plaintiff. If you fail to file an Answer, judgment by default may be entered against you for the relief demanded in the complaint.

*Clerk of the Court*

Aaron M. Levine

Name of Plaintiff's Attorney

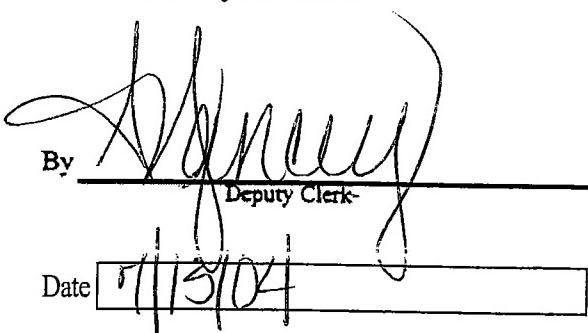
1320 19th St., NW, Suite 500

Address

Washington, DC 20036

(202) 833-8040

Telephone

By \_\_\_\_\_  
  
Deputy Clerk \_\_\_\_\_  
Date 07/13/04

PUEDE OBTENERSE COPIAS DE ESTE FORMULARIO EN ESPANOL EN EL TRIBUNAL SUPERIOR DEL DISTRITO DE COLUMBIA, 500 INDIANA AVENUE, N.W., SALA JM 170

YOU MAY OBTAIN A COPY OF THIS FORM IN SPANISH AT THE SUPERIOR COURT OF D.C., 500 INDIANA AVENUE, N.W., ROOM JM 170

CA Form 1

**Superior Court of the District of Columbia  
CIVIL DIVISION**

500 Indiana Avenue, N.W., Room JM-170  
Washington, D.C. 20001 Telephone: 879-1133

KIMBERLY C. CUTONE, et al.

*Plaintiff*

vs.

Civil Action No.   0002307-04

DART INDUSTRIES, INC.

*Defendant*

**SUMMONS**

To the above named Defendant:

You are hereby summoned and required to serve an Answer to the attached Complaint, either personally or through an attorney, within twenty (20) days after service of this summons upon your exclusive of the day of service. If you are being sued as an officer or agency of the United States Government or the District of Columbia Government you have 60 days after service of this summons to serve your Answer. A copy of the Answer must be mailed to the attorney for the party plaintiff who is suing you. The attorney's name and address appear **below**. If plaintiff has no attorney, a copy of the Answer must be mailed to the plaintiff at the address stated on this Summons.

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*Clerk of the Court*

Aaron M. Levine

Name of Plaintiff's Attorney

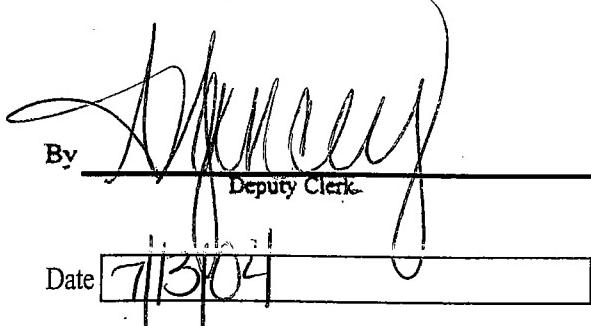
1320 19th St., NW, Suite 500

Address

Washington, DC 20036

(202) 833-8040

Telephone

  
By \_\_\_\_\_ Deputy Clerk \_\_\_\_\_  
Date 7/13/04

PUEDE OBTENERSE COPIAS DE ESTE FORMULARIO EN ESPANOL EN EL TRIBUNAL SUPERIOR DEL DISTRITO DE COLUMBIA, 500 INDIANA AVENUE, N.W., SALA JM 170

YOU MAY OBTAIN A COPY OF THIS FORM IN SPANISH AT THE SUPERIOR COURT OF D.C., 500 INDIANA AVENUE, N.W., ROOM JM 170

CA Form 1

**Superior Court of the District of Columbia  
CIVIL DIVISION**

500 Indiana Avenue, N.W., Room JM-170  
Washington, D.C. 20001 Telephone: 879-1133

KIMBERLY C. CUTONE, et al.

*Plaintiff*

vs.

0005607-04  
Civil Action No. [redacted]

PHARMACIA AND UPJOHN COMPANY

*Defendant*

**SUMMONS**

To the above named Defendant:

You are hereby summoned and required to serve an Answer to the attached Complaint, either personally or through an attorney, within twenty (20) days after service of this summons upon your exclusive of the day of service. If you are being sued as an officer or agency of the United States Government or the District of Columbia Government you have 60 days after service of this summons to serve your Answer. A copy of the Answer must be mailed to the attorney for the party plaintiff who is suing you. The attorney's name and address appear **below**. If plaintiff has no attorney, a copy of the Answer must be mailed to the plaintiff at the address stated on this Summons.

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*Clerk of the Court*

Aaron M. Levine

Name of Plaintiff's Attorney

1320 19th St., NW, Suite 500

Address

Washington, DC 20036

(202) 833-8040

Telephone

By

Deputy Clerk

Date

7/13/04

PUEDE OBTENERSE COPIAS DE ESTE FORMULARIO EN ESPANOL EN EL TRIBUNAL SUPERIOR DEL DISTRITO DE COLUMBIA, 500 INDIANA AVENUE, N.W., SALA JM 170

YOU MAY OBTAIN A COPY OF THIS FORM IN SPANISH AT THE SUPERIOR COURT OF D.C., 500 INDIANA AVENUE, N.W., ROOM JM 170

CA Form 1

**Superior Court of the District of Columbia  
CIVIL DIVISION**

500 Indiana Avenue, N.W., Room JM-170  
Washington, D.C. 20001 Telephone: 879-1133

KIMBERLY C. CUTONE, et al.

*Plaintiff*

vs.

Civil Action No. 0005307-D

ELI LILLY AND COMPANY

*Defendant*

**SUMMONS**

To the above named Defendant:

You are hereby summoned and required to serve an Answer to the attached Complaint, either personally or through an attorney, within twenty (20) days after service of this summons upon your exclusive of the day of service. If you are being sued as an officer or agency of the United States Government or the District of Columbia Government you have 60 days after service of this summons to serve your Answer. A copy of the Answer must be mailed to the attorney for the party plaintiff who is suing you. The attorney's name and address appear **below**. If plaintiff has no attorney, a copy of the Answer must be mailed to the plaintiff at the address stated on this Summons.

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*Clerk of the Court*

Aaron M. Levine

Name of Plaintiff's Attorney

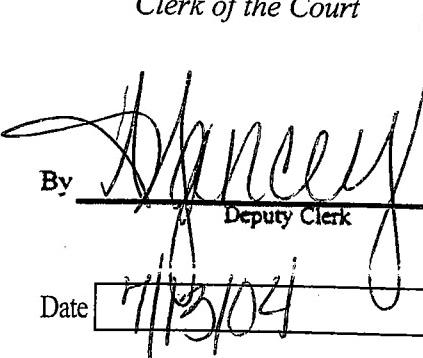
1320 19th St., NW, Suite 500

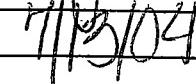
Address

Washington, DC 20036

(202) 833-8040

Telephone

By   
Deputy Clerk

Date 

PUEDE OBTENERSE COPIAS DE ESTE FORMULARIO EN ESPANOL EN EL TRIBUNAL SUPERIOR DEL DISTRITO DE COLUMBIA, 500 INDIANA AVENUE, N.W., SALA JM 170

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CA Form 1

Superior Court of the District of Columbia  
CIVIL DIVISION

500 Indiana Avenue, N.W., Room JM-170  
Washington, D.C. 20001 Telephone: 879-1133

KIMBERLY C. CUTONE, et al.

0003307-04

*Plaintiff*

vs.

Civil Action No. [redacted]

BRISTOL-MYERS SQUIBB COMPANY

*Defendant*

SUMMONS

To the above named Defendant:

You are hereby summoned and required to serve an Answer to the attached Complaint, either personally or through an attorney, within twenty (20) days after service of this summons upon your exclusive of the day of service. If you are being sued as an officer or agency of the United States Government or the District of Columbia Government you have 60 days after service of this summons to serve your Answer. A copy of the Answer must be mailed to the attorney for the party plaintiff who is suing you. The attorney's name and address appear below. If plaintiff has no attorney, a copy of the Answer must be mailed to the plaintiff at the address stated on this Summons.

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Aaron M. Levine

Name of Plaintiff's Attorney

1320 19th St., NW, Suite 500

Address

Washington, DC 20036

(202) 833-8040

Telephone

*Clerk of the Court*

By \_\_\_\_\_

*Deputy Clerk*

Date

7/13/04

PUEDE OBTENERSE COPIAS DE ESTE FORMULARIO EN ESPANOL EN EL TRIBUNAL SUPERIOR DEL DISTRITO DE COLUMBIA, 500 INDIANA AVENUE, N.W., SALA JM 170

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CA Form 1

**Superior Court of the District of Columbia  
CIVIL DIVISION**

500 Indiana Avenue, N.W., Room JM-170  
Washington, D.C. 20001 Telephone: 879-1133

KIMBERLY C. CUTONE, et al.

0003307-04

*Plaintiff*

vs.

Civil Action No. [redacted]

WYETH-AYERST LABORATORIES

*Defendant*

**SUMMONS**

To the above named Defendant:

You are hereby summoned and required to serve an Answer to the attached Complaint, either personally or through an attorney, within twenty (20) days after service of this summons upon your exclusive of the day of service. If you are being sued as an officer or agency of the United States Government or the District of Columbia Government you have 60 days after service of this summons to serve your Answer. A copy of the Answer must be mailed to the attorney for the party plaintiff who is suing you. The attorney's name and address appear below. If plaintiff has no attorney, a copy of the Answer must be mailed to the plaintiff at the address stated on this Summons.

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*Clerk of the Court*

Aaron M. Levine

Name of Plaintiff's Attorney

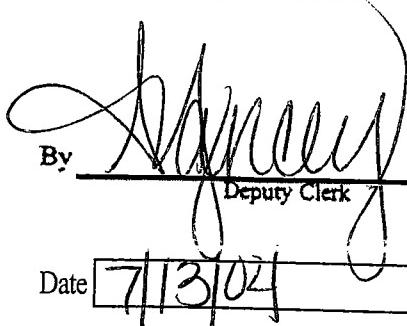
1320 19th St., NW, Suite 500

Address

Washington, DC 20036

(202) 833-8040

Telephone

  
By \_\_\_\_\_  
Deputy Clerk \_\_\_\_\_  
Date 7/13/04

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**Superior Court of the District of Columbia**  
**CIVIL DIVISION — CIVIL ACTIONS BRANCH**

**INFORMATION SHEET**

KIMBERLY C. CUTONE, et al.

vs.

ELI LILLY AND COMPANY, et al.

Case Number:

Date:

Name:

Aaron M. Levine, Esq.

Firm Name:

Aaron M. Levine and Associates

Telephone No.:  Unified Bar No.:

(202) 833-8040

7864

Relationship to Lawsuit

Attorney for Plaintiff

Self (Pro Se)

Other:

12 Person Jury

TYPE OF CASE:  Non-Jury  6 Person Jury

Demand: \$  5,000,000.00

Other:

**PENDING CASE(S) RELATED TO THE ACTION BEING FILED**

Case No. <input type="text"/>	Judge <input type="text"/>	Calendar # <input type="text"/>
Case No. <input type="text"/>	Judge <input type="text"/>	Calendar # <input type="text"/>

NATURE OF SUIT: (*Check One Box Only*)

**A. CONTRACTS**

- |   |   |
|---|---|
| <input type="checkbox"/> 01 Breach of Contract    | <input type="checkbox"/> 07 Personal Property         |
| <input type="checkbox"/> 02 Breach of Warranty    | <input type="checkbox"/> 09 Real Property-Real Estate |
| <input type="checkbox"/> 06 Negotiable Instrument | <input type="checkbox"/> 12 Specific Performance      |
| <input type="checkbox"/> 15 Other: _____          |   |

**COLLECTION CASES**

- |   |
|---|
| <input type="checkbox"/> 14 Under \$25,000 Pltf. Grants Consent |
| <input type="checkbox"/> 16 Under \$25,000 Consent Denied       |
| <input type="checkbox"/> 17 OVER \$25,000                       |

**B. PROPERTY TORTS**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> 01 Automobile                    | <input type="checkbox"/> 03 Destruction of Private Property | <input type="checkbox"/> 05 Trespass     |
| <input type="checkbox"/> 02 Conversion                    | <input type="checkbox"/> 04 Property Damage                 | <input type="checkbox"/> 06 Other: _____ |
| <input type="checkbox"/> 07 Shoplifting, D.C. Code § 3441 |   |  |

**C. PERSONAL TORTS**

- |  |  |
|--|--|
| <input type="checkbox"/> 01 Abuse of Process           | <input type="checkbox"/> 09 Harassment             |
| <input type="checkbox"/> 02 Alienation of Affection    | <input type="checkbox"/> 10 Invasion of Privacy    |
| <input type="checkbox"/> 03 Assault and Battery        | <input type="checkbox"/> 11 Libel and Slander      |
| <input type="checkbox"/> 04 Automobile                 | <input type="checkbox"/> 12 Malicious Interference |
| <input type="checkbox"/> 05 Deceit (Misrepresentation) | <input type="checkbox"/> 13 Malicious Prosecution  |
| <input type="checkbox"/> 06 False Accusation           | <input type="checkbox"/> 14 Malpractice Legal      |
| <input type="checkbox"/> 07 False Arrest               | <input type="checkbox"/> 15 Malpractice Medical    |
| <input type="checkbox"/> 08 Fraud                      | <input checked="" type="checkbox"/> 16 Negligence  |

- |  |
|--|
| <input checked="" type="checkbox"/> 17 Personal Injury |
| <input type="checkbox"/> 18 Wrongful Death             |
| <input type="checkbox"/> 19 Wrongful Eviction          |
| <input type="checkbox"/> 20 Other: _____               |
| <input type="checkbox"/> 21 Asbestos                   |
| <input type="checkbox"/> 22 Toxic/Mass Torts           |

SUPERIOR COURT OF THE DISTRICT OF COLUMBIA

04ca005307 DOCKET

AS OF 8/09/04

EP2003

CAPTION: Cutone,K. et. al. vs. Eli Lilly and Co. et. a  
ASSIGNED JUDGE Michael L. RankinUSER:Wiggins, Vondell  
DEPT:CivC1k

FILED/ EVENT	PARTIES/ ENTRIES	DOCKETED
P001	Kimberly Cutone	
P001A	Aaron M. Levine, Esq. 1320 19th St., N.W. Suite 500 Washington, D.C. 20036	bar#007864
P001B	Brandon J. Levine, Esq. 1320 19th St, NW Ste# 500 Washington DC 20036	bar#412130
P001C	Renee L. Robinson-Meyer, Esq. 1320 19th St., N.W. Suite 500 Washington, D.C. 20036	bar#455375
P001D	Steven J Lewis Aaron M Levine & Associates 1320 19th Street Nw #500 Washington, Dc 20036-1610	bar#472564
P002	Anthony Cutone	
P002A	see previous bar#007864	
P002B	see previous bar#412130	
P002C	see previous bar#455375	
P002D	see previous bar#472564	
VS		
D001	Eli Lilly & Co	
D001A	Lawrence H Martin 1875 K Street, NW Suite 800 Washington, DC 20006	bar#476639
D002	Bristol-Myers Squibb Co	
D002A	Sidney G. Leech, Esq.	bar#359071

CAPTION: Cutone,K. et. al. vs. Eli Lilly and Co. et. a  
 ASSIGNED JUDGE Michael L. Rankin

USER:Wiggins, Vondell  
 DEPT:CivClk

FILED/ EVENT	PARTIES/ ENTRIES	DOCKETED
	One South St. 20th Floor Baltimore, MD 21202	
D003	Pharmacia & Upjohn Co	
D003	(Pro se ) 100 Route 206 North Peapack NJ 07977	
D004	Dart Industries Inc	
D004A	John F Anderson, Esq. 1660 International Drive Suite 600 McLean, VA 22102	bar#393764
D005	Premo Pharmaceutical Labs Inc	
D005A	Juli Z. Simonyi, Esq. 2001 S St., N.W. Suite #310 Washington, D.C. 20009	bar#466921
D006	Wyeth-Ayerst Labs	
D006A	Frank L Heard Iii Williams & Connolly 725 12th Street, N.W. Washington, D.C. 20005	bar#291724
07/12/04	Complaint for personal injury	07/13/04
07/23/04	ANSWER to complaint By Dart Industries BY Dart	07/27/04
07/28/04	ANSWER to complaint by Bristol-Myers Squibb Company's BY Brostol	07/29/04
07/30/04	AFFIDAVIT of service of summons and complaint by mail on pharmacia & upjohn co on date unknown BY (clerk)	08/02/04
07/30/04	AFFIDAVIT of service of summons and complaint by mail on	08/02/04

CAPTION: Cutone,K. et. al. vs. Eli Lilly and Co. et. a  
 ASSIGNED JUDGE Michael L. Rankin

USER:Wiggins, Vondell  
 DEPT:CivClk

FILED/ EVENT	PARTIES/ ENTRIES	DOCKETED
	eli lilly & company on 7-14-04 BY (clerk)	
07/30/04	AFFIDAVIT of service of summons and complaint by mail on premo pharmaceutical laboratories,inc on 7-15-04 BY (clerk)	08/02/04
07/30/04	AFFIDAVIT of service of summons and complaint by mail on wyeth-ayerst laboratories on 7-13-04 BY (clerk)	08/02/04
08/03/04	ANSWER to complaint By Eli Lilly & Company BY Eli	08/05/04
08/04/04	ANSWER to complaint Pharmacisa & Upjohn BY Pharmacia	08/05/04
08/04/04	ANSWER to complaint By Premo Pharmaceutical Lab Inc BY Premo	08/06/04
08/05/04	Financial Disclosure Statement BY Wyeth	08/06/04
08/05/04	ANSWER to complaint by WYETH'S BY WYETH'S	08/06/04
10/15/04	Initial SCHEDULING conference @ 9:30am FSDATE: 041015ss	-SCDC-ss

CAPTION: Cutone,K. et. al. vs. Eli Lilly and Co. et. a  
ASSIGNED JUDGE Michael L. Rankin

USER:Wiggins, Vondell  
DEPT:CivClk

Codes Embedded in Docket Entries

---

(cns) - cancelled by consolidation  
(den) - denied  
(fin) - final disposition  
(jsd) - cancelled by disposition  
(gra) - granted  
(hrg) - hearing  
(mot) - motion opposition due  
(ord) - order  
(opp) - opposition to motion  
(prt) - partial disposition  
(rej) - rejected  
(rst) - rescheduled  
(wdr) - withdrawn

(cn1) - Captioned case is the lead case in consolidated group  
(case#) - Captioned case is subsidiary to (lead case)

FSDATE: - first scheduled date  
NSDATE: - next scheduled date

LSDATE: - last scheduled date

INTRATE - interest rate

INTDATE - interest as of date

Exhibit B

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
Civil Division

KIMBERLY C. CUTONE, and  
ANTHONY CUTONE  
54 Gould Street  
West Roxbury, MA 02132

Plaintiffs,

v.

ELI LILLY AND COMPANY  
Lilly Corporation Center  
Indianapolis, IN 46285  
w/s/o NATIONAL REGISTERED  
AGENTS, INC.  
1090 Vermont Avenue, N.W., Suite 910  
Washington, DC 20005

and

BRISTOL-MYERS SQUIBB COMPANY  
a successor of E.R. SQUIBB & SONS, INC.  
P.O. Box 4500  
Princeton, NJ 08543  
w/s/o CT CORPORATION  
1025 Vermont Avenue, N.W.  
Washington, DC 20005

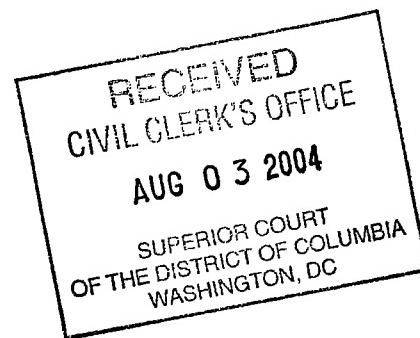
and

PHARMACIA and UPJOHN COMPANY  
(aka THE UPJOHN COMPANY)  
100 Route 206 North  
Peapack, NJ 07977  
w/s/o CT CORPORATION  
1025 Vermont Avenue, N.W.  
Washington, DC 20005

and

DART INDUSTRIES, INC., a successor to  
REXALL DRUG COMPANY, INC.  
14901 South Orange Blossom Trail  
Orlando, FL 32837

w/s/o Sheila AnnMarie Moeller, Esq.  
Gilbride, Tusa, Last & Spellane, LLC  
31 Brookside Drive  
Greenwich, CT 06836



CIVIL ACTION No. 04-0005307

and

PREMO PHARMACEUTICAL  
LABORATORIES, INC.,  
a New Jersey Corporation,  
w/s/o Corporation Trust Company  
820 Bear Tavern Road  
West Trenton, NJ 08628

and

WYETH-AYERST LABORATORIES  
P.O. Box 8299  
Philadelphia, PA 19101

Defendants.

**DEFENDANT ELI LILLY AND COMPANY'S  
ANSWER TO THE COMPLAINT**

Defendant Eli Lilly and Company ("Lilly"), by its undersigned attorneys, answers the Complaint filed in this action as follows:

**FIRST DEFENSE**

Answers to each paragraph of the Complaint by Lilly are made without waiving, but expressly reserving all rights that Lilly may have to seek relief by appropriate motions directed to the allegations of the Complaint.

1. Whether jurisdiction exists in this court pursuant to 11 D.C. Code § 921 (1981 ed.) is a legal question to which no response is required. To the extent a response is required, however,

Lilly denies the allegations contained in Paragraph 1 of the Complaint.

2. Lilly states that it did sell and distribute diethylstilbestrol in the District of Columbia.

Lilly also states that the term "DES" includes many drug products including but not limited to diethylstilbestrol, and any admissions in this Answer are intended to refer only to diethylstilbestrol as it relates to Lilly. Lilly further states that the U.S. Food and Drug

Administration ("FDA") approved Lilly's sales of diethylstilbestrol and declared that the drug

was generally recognized as safe by experts in the field for the uses at issue here. Except as already stated, Lilly denies the allegations contained in Paragraph 2 of the Complaint.

**COUNT I**  
**(Negligence)**

3. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first two sentences and the last sentence of Paragraph 3. Lilly states that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol. Except as already stated, Lilly denies the allegations of Paragraph 3 of the Complaint.

4. Lilly denies the allegations contained in Paragraph 4 of the Complaint.

5. Lilly denies the allegations contained in Paragraph 5 of the Complaint.

**COUNT II**  
**(Strict Liability)**

6. Lilly repeats and realleges its answers contained in Paragraphs 1 through 5 above.

7. Lilly denies the allegations contained in Paragraph 7 of the Complaint.

8. In response to the allegations contained in Paragraph 8, Lilly states that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol. Except as already stated, Lilly denies the allegations of Paragraph 8 of the Complaint.

9. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9. To the extent a response is required, however, Lilly denies the allegations contained in Paragraph 9 of the Complaint.

10. Lilly denies the allegations contained in Paragraph 10 of the Complaint.

11. Lilly denies the allegations contained in Paragraph 11 of the Complaint.

12. Lilly denies the allegations contained in Paragraph 12 of the Complaint.

13. Lilly denies the allegations contained in Paragraph 13 of the Complaint.

**COUNT III**  
**(Breach of Warranty)**

14. Lilly repeats and realleges its answers contained in Paragraphs 1 through 13 above.

15. Lilly denies the allegations contained in Paragraph 15 as stated, but admits that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol for treatment of certain accidents of pregnancy as referenced in its product literature.

16. Lilly denies the allegations contained in Paragraph 16 of the Complaint.

17. Lilly denies the allegations contained in Paragraph 17 of the Complaint.

18. Lilly denies the allegations contained in Paragraph 18 of the Complaint.

**COUNT IV**  
**(Misrepresentation)**

19. Lilly repeats and realleges its answers contained in Paragraphs 1 through 18 above.

20. Lilly denies the allegations contained in Paragraph 20 as stated, but admits that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol for treatment of certain accidents of pregnancy as referenced in its product literature.

21. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 21. To the extent a response is required, however, Lilly denies the allegations contained in Paragraph 21 of the Complaint.

22. Lilly denies the allegations contained in Paragraph 22 of the Complaint.

23. Lilly denies the allegations contained in Paragraph 23 of the Complaint.

**COUNT V**  
**(Punitive Damages)**

24. Lilly repeats and realleges its answers contained in Paragraphs 1 through 23 above.
25. Lilly denies the allegations contained in Paragraph 25 of the Complaint.

**COUNT VI**  
**(Loss of Consortium -- Anthony Cutone)**

26. Lilly repeats and realleges its answers contained in Paragraphs 1 through 25 above.
27. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 27. To the extent a response is required, however, Lilly denies the allegations contained in Paragraph 27 of the Complaint.

**SECOND DEFENSE**

The Complaint fails to state a claim upon which relief can be granted against Lilly.

**THIRD DEFENSE**

The Plaintiffs' claims are barred by the applicable statute of limitations or laches.

**FOURTH DEFENSE**

If Plaintiff sustained injuries or incurred expenses as alleged, the risks complained of by Plaintiff were not discoverable using prevailing research and scientific techniques under the then-existing state of the art and were not discoverable using procedures required by federal and state regulatory authorities charged with supervision or licensing of the product as of the time Lilly sold or otherwise parted with possession and control of the product in question.

**FIFTH DEFENSE**

If Plaintiff sustained injuries or incurred expenses as alleged, Plaintiff's claims may be barred by virtue of the intervention of a learned intermediary or intermediaries to whom defendant discharged any duty to warn.

**SIXTH DEFENSE**

This court lacks personal jurisdiction over defendant.

**SEVENTH DEFENSE**

Venue is improper in this judicial district.

**EIGHTH DEFENSE**

Plaintiff's claims are barred and preempted by Lilly's compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. and/or the regulations promulgated pursuant to that Act.

**NINTH DEFENSE**

Lilly hereby gives notice that it intends to rely upon other and further defenses as may become available or apparent during discovery proceedings in this case, and hereby reserves the right to amend its Answer to assert any such defense.

**DEMAND FOR JURY TRIAL**

The answering defendant requests a trial by jury.

Respectfully submitted,

ELI LILLY AND COMPANY

L.H.Martin

Lawrence H. Martin, D.C. Bar No. 476639  
Foley Hoag LLP  
1875 K Street NW, Suite 800  
Washington, DC 20006-1238  
(202) 223-1200

and

James J. Dillon, D.C. Bar No. 485593  
Foley Hoag LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210-2600  
(617) 832-1000

Dated: August 3, 2004

**CERTIFICATE OF SERVICE**

I certify that on August 3, 2004, a true copy of Defendant Eli Lilly's Answer To The Complaint was served by U.S. First Class Mail, postage prepaid, upon:

Aaron M. Levine, Esq.  
Aaron M. Levine & Associates, P.A.  
1320 Nineteenth Street, N.W., Suite 500  
Washington, DC 20036  
**Attorney for Plaintiff**

Sydney G. Leech, Esq.  
Goodell, DeVries, Leech & Dann, LLP  
One South Street, 20th Floor  
Baltimore, MD 21202  
**Attorney for Bristol-Myers Squibb Company**

Michael McManus, Esq.  
Elizabeth Ewert, Esq.  
Drinker Biddle & Reath  
1500 K Street, N.W., Suite 1100  
Washington, DC 20005-1209  
**Attorneys for Pharmacia and Upjohn Company**

John Anderson, Esq.  
Troutman Sanders LLP  
1660 International Drive  
Suite 600, Tysons Center  
McLean, VA 22102  
**Attorney for Dart Industries, Inc.**

Aaron Handleman, Esq.  
Juli Simonyi, Esq.  
Eccleston and Wolf, P.C.  
2001 S Street, N.W., Suite 310  
Washington, D.C. 20009  
**Attorneys for Premo Pharmaceutical Laboratories, Inc.**

Christopher Garvey, Esq.  
Melanie H. Muhlstock, Esq.  
Goodwin Proctor LLP  
599 Lexington Avenue  
New York, NY 10022  
**Of Counsel for Premo Pharmaceutical Laboratories Inc.**

Willis N. Sautter, Esq.  
Williams & Connolly LLP  
725 Twelfth Street NW  
Washington, DC 20005  
**Attorney Wyeth-Ayerst Laboratories**

  
\_\_\_\_\_  
Lawrence H. Martin

Exhibit C

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
CIVIL DIVISION

KIMBERLY C. CUTONE and  
ANTHONY CUTONE,

Plaintiff,

v.

ELI LILLY AND COMPANY, *et al.*

Defendants.

CIVIL ACTION No. 04-0005307

Calendar #2

Judge Michael L. Rankin

**CONSENT TO REMOVAL**

Bristol-Myers Squibb Company, acting through its attorneys, Sidney G. Leech and Goodell, DeVries, Leech and Dann, LLP, hereby consents to the removal of the above-captioned case from the Superior Court of the District of Columbia to the United States District Court for the District of Columbia.

*Sidney Leech /BH/*  
\_\_\_\_\_  
Sidney G. Leech, D.C. Bar No. 359071  
Goodell, DeVries, Leech & Dann, LLP  
One South Street, 20th Floor  
Baltimore, MD 21202

Attorneys for Defendant, Bristol-Myers  
Squibb Company

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
CIVIL DIVISION

KIMBERLY C. CUTONE and  
ANTHONY CUTONE,

Plaintiff,

v.

ELI LILLY AND COMPANY, *et al.*

Defendants.

CIVIL ACTION No. 04-0005307

Calendar #2

Judge Michael L. Rankin

**CONSENT TO REMOVAL**

Pharmacia and Upjohn Company, acting through its attorneys, Elizabeth Ewert and Drinker Biddle, hereby consents to the removal of the above-captioned case from the Superior Court of the District of Columbia to the United States District Court for the District of Columbia.

*Elizabeth Ewert /B14/*  
Elizabeth Ewert, D.C. Bar No. 479368  
Drinker, Biddle & Reath  
1500 K Street, N.W., Suite 1100  
Washington, DC 20005

Attorneys for Defendant, Pharmacia and Upjohn Company

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
CIVIL DIVISION

KIMBERLY C. CUTONE and  
ANTHONY CUTONE,

Plaintiff,

v.

ELI LILLY AND COMPANY, *et al.*

Defendants.

CIVIL ACTION No. 04-0005307

Calendar #2

Judge Michael L. Rankin

**CONSENT TO REMOVAL**

Dart Industries, Inc., acting through its attorneys, John F. Anderson and Troutman Sanders LLP, hereby consents to the removal of the above-captioned case from the Superior Court of the District of Columbia to the United States District Court for the District of Columbia.

*John Anderson /BA/*  
John F. Anderson, D.C. Bar No. 393764  
Troutman Sanders LLP  
1660 International Drive, Suite 600  
McLean, VA 22102

Attorneys for Defendant, Dart Industries,  
Inc.

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
CIVIL DIVISION

KIMBERLY C. CUTONE and  
ANTHONY CUTONE,

Plaintiff,

v.

ELI LILLY AND COMPANY, *et al.*

Defendants.

CIVIL ACTION No. 04-0005307

Calendar #2

Judge Michael L. Rankin

**CONSENT TO REMOVAL**

Premo Pharmaceutical Laboratories, Inc., acting through its attorneys, Juli Simonyi, Aaron Handleman, and Eccleston & Wolf P.C., consents to the removal of the above-captioned case from the Superior Court of the District of Columbia to the United States District Court for the District of Columbia.

*Juli Simonyi /BH/*  
Juli Z. Simonyi, Bar No. 466921  
Aaron Handleman, Bar No. 48728  
Eccleston & Wolf P.C.  
2001 S Street N.W. #310  
Washington, DC 20009

Attorneys for Defendant, Premo  
Pharmaceutical Laboratories, Inc.

SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA  
Civil Division

KIMBERLY C. CUTONE, and  
ANTHONY CUTONE

Plaintiffs,

v.

ELI LILLY AND COMPANY, *et al.*

Defendants.

CIVIL ACTION No. 04-0005307

**CONSENT TO REMOVAL**

Defendant Wyeth, on behalf of itself and its unincorporated division Wyeth Pharmaceuticals,<sup>1</sup> acting through its attorneys, Lane Heard and Williams & Connolly LLP, hereby consents to the removal of the above-captioned case from the Superior Court of the District of Columbia to the United States District Court for the District of Columbia.



Lane Heard, D.C. Bar No. 291724  
Williams & Connolly LLP  
725 Twelfth Street, N.W.  
Washington, DC 20005

Attorneys for Defendant Wyeth

<sup>1</sup> Wyeth-Ayerst Laboratories, the named defendant, was an unincorporated division of American Home Products Corporation. American Home Products Corporation changed its name to Wyeth on March 11, 2002. The division formerly known as Wyeth-Ayerst Laboratories is now known as Wyeth Pharmaceuticals.